RULES
OF
DEPARTMENT OF COMMUNITY HEALTH

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HEALTH PLANNING

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111-2-1-.01 Definitions.

(1) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-5A-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(2) "Commissioner" means the commissioner of community health established under O.C.G.A. § 31-5A-6.

(3) "Department" means the Department of Community Health established under O.C.G.A. § 31-5A-4.(4) "Health Strategies Council" or "Council" as defined at O.C.G.A. § 31-6-2(10) means the body created by O.C.G.A. § 31-6-20, to advise the Department and adopt the State Health Plan.

(5) "Review Board" as defined at O.C.G.A. § 31-6-2(21) means the Health Planning Review Board created by O.C.G.A. § 31-6-44 to hear and make determinations regarding appeals of decisions of the Department related to applications for a Certificate of Need.

(6) "State Health Plan" as defined at O.C.G.A. § 31-6-2(23) means a comprehensive program adopted by the Health Strategies Council, approved by the Board of Community Health, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the State.

111-2-1-.02 Health Planning Functions of the Department.

(1) The Department is authorized to administer the health planning and certificate of need programs established under O.C.G.A. Title 6 and a state health plan adopted by the Health Strategies Council and approved by the Board. The Department shall provide by rule for procedures to administer its functions. As appropriate, the Commissioner may delegate the authority to administer any function or duty prescribed by law or these Rules to one or more authorized designees in the Division of Health Planning and the Office of General Counsel.

(2) The functions of the Department shall be:

(a) to conduct the health planning activities of the State and, within appropriations made available by the General Assembly and consistent with the laws of the State of Georgia, to implement such parts of the State Health Plan as may relate to State government;

(b) to prepare and revise a draft State Health Plan for submission to the Health Strategies Council for adoption and submission to the Board of Community Health;

(c) to assist the Health Strategies Council in its functions;

(d) to adopt, promulgate, and implement rules and procedures necessary to carry out the provisions of O.C.G.A. § 31-6 in accordance with O.C.G.A. § 50-13, the ”Georgia Administrative Procedure Act.”

(e) to define the form, content, schedules, fees, and procedures for submission of applications for Certificates of Need and periodic reports;

(f) to establish time periods and procedures consistent with O.C.G.A. § 31-6 to hold hearings and to obtain the viewpoints of interested persons prior to issuance or denial of a Certificate of Need;

(g) to provide for such payment as may be necessary to share the costs of preparing the record for Certificate of Need appeals before the Review Board;

(h) to provide for a reasonable and equitable fee schedule for Certificate of Need applications; and

(i) to grant, deny, suspend, rescind, cancel, or revoke a Certificate of Need as applied for or as amended.

(j) to impose civil penalties as permitted or required by law for violation of these Rules and O.C.G.A. § 31-6.

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111-2
HEALTH PLANNING

111-2-2
Certificate of Need

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111-2-2-.01 Definitions.

As used in these Rules, the term:

(1) “Acquisition of an existing health care facility” means to come into possession or control of a health care facility by purchase, gift, merger of corporations, lease, purchase of stock, inheritance, or by any other legal means.

(2) “Acquisition of diagnostic or therapeutic equipment”:

(a) as it relates to a diagnostic, treatment, or rehabilitation center, means to come into possession, or control of, or to otherwise use diagnostic or therapeutic equipment by purchase, gift, donation, lease, transfer, or by any other legal means by or on behalf of the diagnostic, treatment, or rehabilitation center; and

(b) as it relates to a health care facility, means to come into possession or control of diagnostic or therapeutic equipment by purchase or lease by or on behalf of the health care facility.

(3) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services (“CMS”), by the Georgia Division of Medical Assistance (“DMA”), by the State Health Benefit Plans, or by any successor entities as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(4) "Ambulatory surgical or obstetrical facility", as defined at O.C.G.A. § 31-6-2(1) means a public or private facility, not a part of a hospital, which provides surgical or obstetrical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization.

(5) "Applicant" means the owner or lessee of an existing health care facility or the person who would be the owner or lessee of a proposed facility, as named in the application. An applicant may also be multiple owners or lessees of existing health care facilities who share common ownership or corporate affiliation and wish to submit an application to the Department for a single Certificate of Need for certain non-clinical health services, for example, but not limited to, parking decks, infrastructure improvement or replacement, and capital renovation expenditures.

(6) “Application”, as defined at O.C.G.A. § 31-6-2(2), means a written request for a Certificate of Need made to the Department, containing such documentation and information as the Department may require.

(7) “Approved date” means the date that the Department issues a Certificate of Need to an applicant.

(8) “Associated with and simultaneously developed or proposed” means that if the Department determines that a single project or the substantial equivalent of a single project is divided into separate components which are associated and which are developed or

planned simultaneously, so that the project or the substantial equivalent of a project or any component thereof does not require a total capital expenditure in excess of the capital expenditure or diagnostic or therapeutic equipment threshold, the Department shall combine the components for purposes of computing the amount of the total capital expenditure or expense and shall treat the combined components as a single project or substantial equivalent of a project. The Department shall include items and expenditures which are related and which occur simultaneously in computing an applicable threshold regardless of whether the items or expenditures individually may otherwise be below the threshold or may be otherwise unreviewable exclusive of the items exempted from review by 111-2-2-.03(1)-(3) and 111-2-2-.03(5)-(19);

(a) The Department may determine that activities, services, expenditures, and items are associated if they share a relationship or association based on law, regulation, definition, function, procedure, or process; and

(b) The Department shall determine that expenditures related to activities, services, and items are simultaneously developed or planned if such expenditures occur within a 6-month period. The 6-month period shall run from operation of the activity, service or item to initial capital expenditure on the second activity or item or from operation of the activity or item to operation of the second activity or item. For services, the date of operation shall be the date that the service is actually offered. If applicable, for facilities, the date of operation shall be the date a Certificate of Occupancy is issued.

(9) Reserved.

(10)"Bed capacity", as defined at O.C.G.A. § 31-6-2(3) means space used exclusively for inpatient care, including space designed or remodeled for inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by Rules of the Department of Human Resources, except that single beds in single rooms shall be counted even if the room contains inadequate square footage.

(11) “By or on behalf of” means any expenditures made by a health care facility, a political subdivision of the State, a diagnostic, treatment, or rehabilitation center, or a hospital authority, itself as well as capital expenditures made by other persons or related entities to assist the facility, subdivision, center, or authority, directly or indirectly, to offer services to its patients or residents. Related entities include entities that are associated or affiliated with, have control over or are controlled by, or have any direct financial interest in, the health care facility, political subdivision of the State, diagnostic, treatment, or rehabilitation center, or hospital authority, including, without limitation, an underwriter, guarantor, parent organization, sister organization, subsidiary or sub-entity, foreign corporation, joint venturer, partner, general partner, or building lessor, as applicable.

(12) “Capital expenditure” in relation to a proposed modification, renovation, or addition to a health care facility or to a diagnostic, treatment, or rehabilitation center, or acquisition of equipment, means an expenditure by or on behalf of a health care facility or diagnostic, treatment, or rehabilitation center that, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. Any series of capital expenditures, each less than a threshold, but which when taken together are in excess of a threshold, directed toward the accomplishment of a single project, requires a Certificate of Need. Any series of capital expenditures, which are associated and simultaneously

developed or proposed, will be presumed to be a single project. In calculating the capital expenditure for modifications, additions, or renovations “capital expenditure” is the amount per construction bid or total amount of invoices or purchase orders for the single project excluding diagnostic or therapeutic equipment.

(13)"Certificate of Need", as defined at O.C.G.A. § 31-6-2(4) means an official determination by the Department, evidenced by certification issued pursuant to an application, that the action proposed in the application satisfies and complies with the criteria contained in the Statute and Rules promulgated pursuant thereto.

(14) Reserved.

(15)"Clinical health services", as defined at O.C.G.A. § 31-6-2(5), means diagnostic, treatment, or rehabilitative services provided in a health care facility, or parts of the physical plant where such services are located in a health care facility, and includes, but is not limited to, the following: radiology and diagnostic imaging, such as magnetic resonance imaging and positron emission tomography; radiation therapy; biliary lithotripsy; surgery; intensive care; coronary care; pediatrics; gynecology; obstetrics; general medical care; medical/surgical care; cardiac catheterization; open-heart surgery; inpatient rehabilitation; and alcohol, drug abuse, and mental health services.

(16) "Consumer", as defined at O.C.G.A. § 31-6-2(6), means a person who is not employed by any health care facility or provider and who has no financial or fiduciary interest in any health care facility or provider.

(17)"Cost estimate” means an estimate of the total cost of a project’s development and construction prepared by a licensed architect or engineer within sixty days prior to the date of submittal of an application.

(18) “Defined location,” as it relates to the approved location of a project or substantial equivalent of a project, means the address of the project, or in the case of a health care facility or diagnostic, treatment, or rehabilitation center with multiple addresses, the campus of such health care facility or diagnostic, treatment, or rehabilitation center. However, in no case shall a campus be considered a single defined location if varying locations and facilities of such campus are more than 3 miles apart or within more than one county.

(19)"Develop", as defined at O.C.G.A. § 31-6-2(7), with reference to a project, means:

(a) constructing, remodeling, installing, or proceeding with a project, or any part of a project, or a capital expenditure project, the cost estimate for which exceeds $900,000.00, which amount shall be adjusted annually as provided by law;

(b) the expenditure or commitment of funds exceeding $500,000.00,which amount shall be adjusted annually as provided by law, for orders, purchases, leases, or acquisitions through other comparable arrangements of new or additional major medical equipment and facilities, including activities, items and services, which are associated with and simultaneously developed or proposed. Reviewability of acquisitions by lease or gift will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure that would be required for purchase. The value of the facilities to be acquired is based on a current (within six months) appraisal of the property; and

(c) Notwithstanding subparagraphs (a) and (b) above, the expenditure or commitment or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications, or working drawings, or to acquire, develop, or prepare sites shall not be considered to be the developing of a project.

(20) "Diagnostic, treatment, or rehabilitation center", as defined at O.C.G.A. § 31-6-2(7.1), means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not part of a hospital.

(21) “Effective date” means:

(a) for approved projects that have not been appealed pursuant to the appeal provisions of the Rules of the Health Planning Review Board, the approved date;

(b) for projects, which are appealed pursuant to the appeal provisions of the Rules of the Health Planning Review Board, the date of the final resolution of any such administrative appeal if the resolution results in the approval of the project; or

(c) for projects which undergo judicial review, the effective date shall be the date referenced in (b) above, unless the Department, pursuant to rule 111-2-2-.07(2)(h), or the reviewing court stays the effective date of the project pending the outcome of the judicial review. If the Department or the reviewing court stays the effective date, the effective date shall be the date of the final resolution of any such judicial review if the resolution results in approval of the project.

(22) “Expiration date” is the date upon which a certificate of need expires and becomes null and void.

(23) “Functionally related diagnostic or therapeutic equipment” means that pieces of diagnostic or therapeutic equipment are interdependent to the extent that one piece of equipment is unable to function in the absence of or without the functioning piece or equipment, or that pieces of equipment are normally used together in the provision of a single health care facility or diagnostic, treatment, or rehabilitation center service.

(24) "Health care facility", as defined at O.C.G.A. § 31-6-2(8), means hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes of at least 25 beds; ambulatory surgical or obstetrical facilities; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitation centers, but only to the extent that O.C.G.A. § 31-6-2(14)(G) or (H) or 111-2-2-.01(33)(h) and (i) of these Rules are applicable thereto; and facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for 24 hours or longer for persons who have traumatic brain injury, as defined in O.C.G.A. § 37-3-1.

(25) "Health maintenance organization", as defined at O.C.G.A. § 31-6-2(9), means a public or private organization organized under the laws of this state which:

(a) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physicians' services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(b) is compensated, except for co-payments, for the provision of the basic health care services listed in subparagraph (a) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(c) provides physicians' services primarily:

1. directly through physicians who are either employees or partners of such organization; or

2. through arrangements with individual physicians organized on a group practice or individual practice basis.

(26) "Home health agency", as defined at O.C.G.A. § 31-6-2(11) means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the places of residence used as such individuals' homes, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services:

(a) physical therapy;

(b) occupational therapy;

(c) speech therapy;

(d) medical social services under the direction of a physician; or

(e) part-time or intermittent services of a home health aide.

(27) "Hospital", as defined at O.C.G.A. § 31-6-2(12), means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term includes public, private, psychiatric, rehabilitative, geriatric, osteopathic, and other specialty hospitals.

(28) “Incur a financial obligation”, in relation to the offering of a new institutional health service, means that, within time periods described in Section 111-2-2-.02(5) and (6) of these Rules, the applicant has fulfilled the following performance requirements.

(a) With regard to new construction or renovation:

1. has acquired title, an option to purchase or a leasehold to an appropriate site;

2. has filed with the Department the complete set of plans, drawings, and specifications for the project;

3. has obtained a firm commitment for adequate capital financing ; and

4. has entered into a construction contract that provides for a specific date for commencement, and completion of construction within a reasonable time span.

(b) With regard to equipment not associated with a construction project;

1. a purchase or lease agreement has been entered into or, if acquired by a comparable arrangement, the applicant has possession of the equipment.

(29) Reserved.

(30) "Intermediate care facility", as defined at O.C.G.A. § 31-6-2(13), means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(31) “Joined applications” means two or more applications which involve similar projects in the same service area or overlapping service areas all of which have been declared complete within thirty days of the date the first application was declared complete, and whose time limits are scheduled to run from the latest date that any one of the joined applications was declared complete for review.

(32) “Mobile unit" means an object with the ability by structure, function or design to move or be moved from one site to another, such that upon arriving at a site the object is not permanently fixed but is temporarily secured for the purpose of providing a service to individuals.

(33) "New institutional health service", as defined at O.C.G.A. § 31-6-2(14) means:

(a) the construction, development, or other establishment of a new health care facility;

(b) any expenditure by or on behalf of a health care facility in excess of $900,000.00, which amount shall be adjusted annually as provided by law, and which, under generally accepted accounting principles consistently applied, is a capital expenditure, except expenditures for acquisition of an existing health care facility not owned or operated by or on behalf of a political subdivision of this state, or any combination of such political subdivisions, or by or on behalf of a hospital authority, as defined in O.C.G.A. § 31-7-4 or certificate of need owned by such facility in connection with its acquisition. See the definition of “threshold” below for expenditures that shall be counted to calculate the threshold;

(c) any increase in the bed capacity of a health care facility, regardless of whether a capital expenditure is made, which increases the total bed capacity. An exception to this rule will be made in accordance with Rule 111-2-2-.03(15);

(d) clinical health services that are offered in or through a health care facility, which were not offered on a regular basis in or through such health care facility within the 12-month period prior to the time such services would be offered;

(e) any conversion or upgrading of a facility such that it is converted from a type of facility not covered by these Rules to any of the types of health care facilities which are covered by these Rules;

(f) the purchase or lease by or on behalf of a health care facility of diagnostic or therapeutic equipment with a value in excess of $500,000.00, which amount shall be adjusted annually as provided by law. See the definition of "threshold" below for expenditures that will be counted to calculate the threshold;

(g) the acquisition of an existing health care facility which is owned or operated by or on behalf of a political subdivision of this State; any combination of such political subdivisions, or by or on behalf of a hospital authority except as otherwise provided in these Rules.

(h) clinical health services which are offered in or through a diagnostic, treatment, or rehabilitation center which were not offered on a regular basis in or through that center within the 12-month period to the time such services would be offered, but only if the clinical health services are any of the following:

1. Radiation therapy;

2. Biliary lithotripsy;

3. Surgery in an operating room environment, including but not limited to ambulatory surgery; provided, however, this provision shall not apply to surgery performed in the offices of an individual private physician or single group practice of private physicians if such surgery is performed in a facility that is owned, operated, and utilized by such physicians who also are of a single specialty and the capital expenditure associated with the construction, development, or other establishment of the clinical health service does not exceed the threshold amount of $1 million, which amount shall be adjusted annually as provided by law. Expenditures and values related to associated with and simultaneously developed or proposed activities shall be counted. See the definition of "threshold" below for expenditures that shall be counted to calculate the threshold; and

4. Cardiac catheterization; or

(i) the purchase, lease, or other use by or on behalf of a diagnostic, treatment, or rehabilitation center of diagnostic or therapeutic equipment with a value in excess of $500,000.00, which amount shall be adjusted annually as provided by law. See the definition of "threshold" below for expenditures that will be counted to calculate the threshold

(34) "Nonclinical health services", as defined at O.C.G.A. § 31-6-2(15), means services or functions provided or performed by a health care facility, and the parts of the physical plant where they are located in a health care facility that are not diagnostic, therapeutic, or

rehabilitative services to patients and are not clinical health services as defined in this chapter.

(35) "Offer", as defined at O.C.G.A. § 31-6-2(16), means that the health care facility is open for the acceptance of patients or performance of services and has qualified personnel, equipment, and supplies necessary to provide specified health services.

(36) "Operating room environment", as defined at O.C.G.A. § 31-6-2(16.1), means an environment which meets the minimum physical plant and operation standards specified on January 1, 1991, for ambulatory surgical treatment centers in Section 290-5-33-.10 of the Rules of the Department of Human Resources.

(37) "Person", as defined at O.C.G.A. § 31-6-2(17), means any individual, trust, or estate, partnership, corporation (including associations, joint-stock companies and insurance companies), state, political subdivision, hospital authority, or instrumentality (including a municipal corporation) of a state as defined in the laws of this State.

(38) "Personal Care Home", as defined at O.C.G.A. § 31-6-2(18), means a residential facility having at least 25 beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes including those facilities which monitor daily residents' functioning and location, have the capacity for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

(a) old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

(b) boarding facilities that do not provide personal care.

(39) "Project", as defined at O.C.G.A. § 31-6-2(20), means a proposal to take an action for which Certificate of Need review is required under these Rules. A project or proposed project may refer to the proposal from its earliest planning stages up through the point at which the new institutional health service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed," the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, which are determined by the Department to be associated with one another, to be a single project.

(40) "Service-specific Rule" means those rules that are part of 111-2-2 that regard specific clinical health care services as outlined at 111-2-2-.20 et seq.

(41) "Skilled nursing facility", as defined at O.C.G.A. § 31-6-2(22), means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(42) "State health plan", as defined at O.C.G.A. § 31-6-2(23), means the comprehensive program adopted by the Health Strategies Council, approved by the Governor, and

implemented by the Department for the purpose of providing adequate health care services and facilities throughout the State. The State Health Plan is divided into a series of component plans modified from time to time as needed.

(43) "Substantial equivalent of a project" means a proposal to take an action for which a letter of non-reviewability or determination is sought under these Rules. A substantial equivalent of a project may refer to the proposal from its earliest planning stages up through the point at which the service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed," the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, which are determined by the Department to be associated with one another, to be a single substantial equivalent of a project.

(44) "Threshold" means the dollar amount of capital expenditures for which, when exceeded, a Certificate of Need is required.

(a) In calculating the dollar amounts of a proposed project for purposes of 111-2-2-.01(19)(a) and (b), and 111-2-2-.01(33)(b), (f), (h)3., and (i) of these Rules, the capital costs (by or on behalf of a health care facility or by or on behalf of a diagnostic, treatment or rehabilitation center) of all items subject to review by these Rules and items not subject to review by these Rules associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop certificate of need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(b) The following threshold amounts are effective as of April 15, 2004:

1. The capital expenditure threshold of 111-2-2-.01(19)(a) and 111-2-2-.01(33)(b), as adjusted according to law, is $ 1,322,451;

2. The equipment threshold of 111-2-2-.01(19)(b) and 111-2-2-.01(33)(f) and (i), as adjusted according to law, equals $734,695;

3. The physician-owned, single-specialty, office-based ambulatory surgery center threshold of 111-2-2-.01(33)(h)3., as adjusted according to law, is $ 1,436,356;

Beginning on or about April 1, 2005, the Department shall update or adjust these CON threshold amounts by the annual percentage of change in an appropriate composite price index that, in the judgment of the Department, represents national construction prices for the preceding calendar year such as those published by the Department of Commerce of the United States government or other government agency;

(c) For purposes of computing the capital expenditure threshold of 111-2-2-.01(33)(b) and 111-2-2-.01(19)(a) and the physician-owned, single specialty ambulatory surgery threshold of 111-2-2-.01(33)(h)3., the Department shall include, but not be limited to, the following guidelines:

1. Pursuant to the definition of "associated with and simultaneously developed or proposed," the total cost of all associated capital expenditures for items to be obligated for or purchased within a six month period for a single program, service, plan, or project, regardless of whether or not the cost of any individual item is in excess of the capital expenditure threshold and regardless of whether or not the expenditure or item is otherwise reviewable under these Rules or the CON Statute, is included in the computation;

2. The cost of depreciable equipment that is not used for diagnosis or treatment, such as office equipment, usual business equipment, and office and waiting room furniture, is included in the computation, if such items are associated with and simultaneously developed or proposed with the project. If such furnishing and equipment are used, the cost that shall be used in calculating the threshold shall be the depreciated value or current market value of the furnishings or equipment, whichever is greater;

3. The cost of normal inventories of supplies, such as glassware, chemicals, drugs, linens, and paper, is exempt from the computation as an operating expense;

4. The value of the facilities to be acquired by lease, gift, donation or other means is based on a current (within six months) appraisal of the facility, except that the value of newly constructed facilities shall be based on the actual square footage cost to construct the facility;

5. For facilities that are acquired by lease, the computation of value shall be based on the rentable square footage of the facility and not the useable square footage. Notwithstanding this Rule, lease payments shall be considered to be operating expenses for leases other than capital leases;

6. For facilities that are only partly occupied by a person, the computation shall include a pro-rata share of the value of the common space, unless the rentable square footage is provided as required by 5 above and that rentable square footage already includes an allocation for common space, as documented by the lease agreement; and

7. In the case of a gift or donation, the value of equipment, furnishings or facilities is the fair market value of the equipment, furnishings, or facilities;

(d) For purposes of computing the equipment threshold of 111-2-2-.01(19)(b), 111-2-2-.01(33)(f) and (33)(i), the Department shall include, but not be limited to, the following guidelines:

1. The cost of diagnostic or therapeutic equipment includes all capital costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended, including but not limited to the following expenses:

(i) Any expense incurred for the purchase of a first year's warranty on the diagnostic or therapeutic equipment from the manufacturer or vendor;

(ii) Any expense incurred for operator training;

(iii) Any expense incurred for installation and assembly of the equipment;

(iv) Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

(v) Any expense incurred for functionally related diagnostic or therapeutic equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.

(vi) Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

(vii) Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

(viii) Any dollar amount attributable to service contracts for the initial year of operation;

(ix) Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of non-reviewability by the manufacturer or vendor of the equipment;

(x) Any expense attributable to facility construction/build-out to make the equipment functional to include, but not to be limited to, electrical and plumbing work to be performed, masonry expenses to lay a concrete pad; and

(xi) For mobile units of equipment, expenditures and values associated with the motor coach, trailer, van, rig, or other form of modular or transitional housing shall be included in the computation of the threshold;

2. The acquisition by whatever means of one or more items of functionally related diagnostic or therapeutic equipment shall be considered as one project. The acquisition of functionally related accessories shall also be counted. Pursuant to the definition of "functionally related diagnostic or therapeutic equipment," any individual components or pieces of diagnostic or therapeutic equipment, which depend on one another in order to function and that are purchased within a 6-month period, shall be considered in the aggregate in calculating the threshold;

3. Diagnostic or therapeutic equipment shall include single and multiple units of equipment, if such units are associated with and simultaneously developed or proposed with one another. Pursuant to the definition of "associated with and

simultaneously developed or proposed, the Department may determine that individual pieces or units of diagnostic or therapeutic equipment are associated with one another if such pieces or units of equipment are used for the same or similar health services and if such pieces or units of equipment are developed, proposed, or acquired simultaneously. Such associated and simultaneous units purchased within a 6-month period shall be aggregated to calculate the threshold;

4. Purchase or lease shall include purchases, contracts, encumbrances of funds, lease arrangements, conditional sales or a comparable arrangements that purport to be a transfer of ownership in whole or in part;

5. In the case of a lease, loan, or gift, the value of the diagnostic or therapeutic equipment is the fair market value of the diagnostic or therapeutic equipment, as evidenced by documentation from a reputable vendor or manufacturer; and

6. Expenditures and values related to associated with and simultaneously developed or proposed activities shall be counted including, but not limited to, construction of space to house the equipment and construction of waiting rooms and office space.

111-2-2-.02 Nature of Certificate of Need.

(1) **Purpose.** The purpose of the Certificate of Need evaluation process is to ensure that adequate health care services and facilities are developed in an orderly and economical manner and are made available to all Georgians and that only those health care services that are found to be in the public interest shall be provided in the State. The goals are to:

(a) Review proposed health care services;

(b) Contain health costs;

(c) Promote economic value;

(d) Ensure compatibility of health care services with the needs of various areas and populations of Georgia; and

(e) Prevent unnecessary duplication or services.

(2) **Contents.** The certificate, or attachments, shall specify, but not be limited to:

(a) the scope of the project;

(b) the defined location of the project;

(c) the person to whom the certificate was issued;

(d) the maximum capital expenditure, if any, which may be obligated under the certificate;

(e) the service area of the project;

(f) the valid dates;

(g) the schedule of time periods to be followed in making the service or equipment available or in completing the project;

(h) the services or units of services, which have been approved; and

(i) when the progress reporting requirements under 111-2-2-.04(2) and 111-2-2-.02(5) are due.

(3) **Validity.** A Certificate of Need shall be valid only for the defined scope, physical location, cost, service area, and person named in the application as the applicant.

(4) **Non-transferability.** A Certificate of Need shall not be transferable or assignable, nor shall a project for which a Certificate of Need has been issued be transferred from or assigned by one person to another, except under the following circumstances:

(a) the death of the holder of the Certificate, provided the transfer is solely from the estate of the holder to his or her heirs; or

(b) an existing licensed health care facility to which a Certificate has been issued is acquired by another person, in which instance the Certificate shall be valid for the person who acquires the facility and for the scope, location, cost, and service area previously approved by the Department.

(5) **Effective Period.** Unless otherwise provided by a service-specific rule, or unless the Department in accordance with 111-2-2-.02(7) has extended the effective period, the effective period of a Certificate of Need shall be as follows:

(a) Certificates involving neither construction nor equipment acquisition shall be effective for 12 months;

(b) Certificates solely involving acquisition of equipment shall be effective for 12 months, by which date the applicant must be in possession of the equipment; and

(c) Certificates for projects involving construction shall be effective based on a reasonable, phased timetable presented in the application, which may be amended during the review cycle, as planned, developed, proposed, and submitted by the applicant. In determining the reasonableness of the proposed phases and time periods, the Department will be guided by the applicable horizon year for the project. However, in appropriate circumstance, the Department may approve an effective period in excess of the applicable horizon year. The approved and valid phases and effective period shall be included in the Certificate of Need. When the Department extends the effective period pursuant to 111-2-2-.02(7) or when, due to an appeal of a project, a project's effective date is not the approved date, the Department will update the effective period, including the horizon year, of the project accordingly.

(6) **Initial 12-month Implementation Period for Projects Involving Construction.** Unless otherwise provided in a service-specific rule or unless the Department in accordance with 111-2-2-.02(7) has extended the initial 12-month implementation period, all projects involving construction regardless of the dollar amount must, within 12 months of the effective date of the certificate, demonstrate, as evidenced by a progress report (as described at 111-2-2-.04(2)) and supporting documentation, substantial performance in beginning the project. Substantial performance shall be demonstrated by the following:

(a) The construction plans have been approved by the Department's Architect;

(b) The construction contract has been signed and specifically indicates beginning and completion dates; and

(c) Construction materials and equipment are on site.

(7) **Extension of Time Periods.** The Department may, upon written request of the certificate holder, grant an extension of the effective period of a Certificate of Need or of the initial 12-month implementation period if the applicant's request is received by the Department 30 days prior to expiration of the Certificate of Need or of the initial 12-month implementation period, as applicable.

(a) A request for an extension of the initial 12-month implementation period, or any extension thereof, shall demonstrate:

1. that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the initial 12-month implementation period may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences. Ordinarily, lack of adequate or accurate planning, uncertainty as to reimbursement and/or financial difficulties will not justify an extension of the implementation period;

2. that the certificate holder has made substantial and timely progress in implementing the project. In order to show substantial and timely progress in implementing the project, the certificate holder must show that the project was on schedule and could reasonably have been implemented during the initial 12-month implementation period or extension thereof, but for the occurrence or circumstance beyond the certificate holder's control;

(b) A request for an extension of the effective period of a certificate of need, or any phase or extension thereof, shall:

1. demonstrate that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the effective period, or any phase or extension thereof, may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences.

2. demonstrate that but for the circumstances beyond the control of the certificate holder, the project, or phase thereof, would have been completed within the effective period;

3. demonstrate that the certificate holder has made substantial and timely progress in completing the project, or phase thereof;

4. indicate the expected completion date of the project, or phase thereof, as applicable; and

5. affirm that the project, or phase thereof, will be completed within the requested extension period.

(c) The length of an extension of the effective period or of the initial 12-month implementation period of a Certificate of Need shall be determined by the Department and shall be reasonable and consistent with the circumstances. In no case, shall the Department extend the initial 12-month implementation period of a Certificate of Need beyond an additional 12 months.

(d) In circumstances where the certificate holder is precluded from normal progression due to litigation involving the Certificate or where the method of financing is precluded by

litigation, the Department may, at its discretion, suspend any or all of the time periods specified herein until the litigation has been resolved.

(8) **Expiration and Cancellation.** If, within the effective period specified in 111-2-2-.02(5) and initial 12-month implementation period specified in 111-2-2-.02(6), as applicable, the required performance standards are not met, the Certificate will be deemed to have expired unless an extension has been obtained from the Department pursuant to 111-2-2-.02(7). Unless the certificate holder demonstrated good cause not to deem the Certificate to have expired, which shall be determined by the Department, the Certificate will be canceled and notifications of same issued to the applicant, local governing authorities, Regional Development Center, and a newspaper of general circulation in the area where the application originated. An applicant whose Certificate has expired may not resubmit an application for the same or a substantially similar project until at least 120 days after expiration of the Certificate.

(9) **Modification by Operation of Law of Certificate for Failure to Complete.** Upon expiration of the effective period, if a certificate holder has not completed all activities or has not implemented all services or units of services granted in the Certificate of Need issued on the approved date (or if appealed, the effective date), the Certificate shall be modified upon such expiration to include and be valid for only those activities, services, or units of services, which have been completed and implemented as of the date of expiration.

111-2-2-.03 Exemptions from Review. The following shall not be subject to Certificate of Need review and shall be exempted from the provisions of these Rules regarding Certificate of Need Review except as otherwise provided:

(1) infirmaries operated by educational institutions for the sole and exclusive benefit of students, faculty members, officers, or employees thereof;

(2) infirmaries or facilities operated by businesses for the sole and exclusive benefit of officers or employees thereof, provided that such infirmaries or facilities make no provision for overnight stay by persons receiving their services;

(3) institutions operated exclusively by the federal government or by any of its agencies;

(4) offices of private physicians or dentists, as determined in the sole discretion of the Department, whether for individual or group practice except as otherwise provided in 111-2-2-.01(33)(h) and 111-2-2-.01(33)(i). Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the scope of these Rules. Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied exclusively as the office of private physicians or dentists. Therefore, any person who seeks licensure as a health care facility must secure a certificate of need if a new institutional health service is being offered or developed;

(5) Christian Science sanatoriums operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts;

(6) site acquisitions for health care facilities or preparation or development costs for such sites prior to filing a Certificate of Need application;

(7) expenditures related to adequate preparation and development of an application for a Certificate of Need;

(8) the commitment of funds conditioned upon the obtaining of a Certificate of Need;

(9) transfers from one health care facility to another such facility of major medical equipment previously approved under or exempted from Certificate of Need review, except where such transfer results in the institution of a new clinical health service for which a Certificate of Need is required in the facility acquiring said equipment, provided that such transfers are recorded at net book value of the medical equipment as recorded on the books of the transferring facility;

(10) expenditures for the acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means, unless the facilities are owned or operated by or on behalf of a:

(a) Political subdivision of this state;

(b) Combination of such political subdivision; or

(c) Hospital authority, as defined in Article 4 of Chapter 7 of Title 31.

(11) expenditures for the restructuring of or for the acquisition by stock or asset purchase, merger, consolidation, or other lawful means of an existing health care facility which is owned or operated by or on behalf of any entity described in 111-2-2-.03(10) only if such restructuring or acquisition is made by any entity described in 111-2-2-.03(10);

(12) expenditures for the repair or replacement of equipment associated with the physical plant, provided the expenditures do not exceed the threshold for capital expenditures;

(13) capital expenditures otherwise covered by this Chapter required solely to eliminate or prevent safety hazards as defined by federal, state or local fire, building, environmental occupational health, or life safety codes of regulations, to comply with licensing requirements of the Department of Human Resources, or to comply with accreditation standards of the Joint Commission on Accreditation of Health Care Organizations;

(14) except as otherwise provided in this subsection, all cost overruns are excluded from prior Certificate of Need review and approval. For purposes of this subsection, a cost overrun that is subject to prior Certificate of Need review and approval (i.e., a reviewable cost overrun) is defined as meaning any cost overrun which is in excess of the current capital or diagnostic or therapeutic equipment threshold, or in excess of 10 percent of the approved capital expenditure amount, whichever is less. However, in no event shall an additional expenditure of less than $300,000 be deemed a reviewable cost overrun. Reviewable cost overruns will be reviewed by the Department in accordance with the following provisions:

(a) A reviewable cost overrun associated with ongoing construction or renovation activity which has not been incurred prior to a Certificate of Need approval and is solely related to an unanticipated engineering, major fixed equipment or other construction problem, or federal, state or local fire requirements which were adopted or became effective after the issuance of the Certificate of Need but prior to the completion of construction or renovation, will receive favorable review consideration if the applicant demonstrates that the overrun will have no impact or a minimal impact on costs and/or charges per patient day or procedure; and

(b) A reviewable cost overrun which is the result of subsequent project bidding prior to any contractual obligation for construction and/or renovation work will not receive favorable review consideration by the Department but will require the entire project to be reviewed as an entirely new project subject to all the applicable criteria, standards and plans; and

(c) A reviewable cost overrun which is due to delays of project construction and/or renovation activity resulting from an appeal proceeding, when such delay has been in excess of one year, and where the Department has suspended the time periods until the issues are resolved, will be given favorable consideration as long as the project has not changed in scope, square footage, services or number of new beds proposed.

(d) For projects involving either construction or renovation, but not both, a reviewable cost overrun which increases the square footage beyond 5 percent of the originally approved project's total new square footage will require the entire project to be

submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(e) For projects involving construction and renovation, a reviewable cost overrun which increases the square footage beyond 5 percent of the sum of the new construction square footage and renovated square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(f) Regardless of cost, during implementation of the project, any increase in the scope of the original project or any change in the number of beds (i.e., the subtraction, addition, replacement or conversion of different number of beds than authorized in the original Certificate of Need) will invalidate the original project and the Department will deem the original project to have been withdrawn unless prior written approval is obtained from the Department.

(15) increases in the bed capacity of a hospital up to ten beds or ten percent of capacity, whichever is less, in any consecutive two-year period, in a hospital that has maintained an overall occupancy rate greater than 85 percent (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous 12 month period;

(16) expenditures for the replacement of diagnostic or therapeutic equipment, including, but not limited to, CT scanners.

(a) To qualify for this exemption, the replaced equipment must have received prior CON review and approval, or have been grandfathered, and the replaced equipment must be removed entirely from the premises and not be used in tandem with the replacement equipment, unless authorized in writing by the Department. Replacement equipment must be placed in the same defined location as the replaced equipment.

1. The Department may authorize in writing the retention of certain functionality of the equipment to be replaced if such retained functionality is not used in tandem with the replacement equipment and if the retained functionality would not otherwise result in the provision of a new institutional health service. The fair market value of the retained functionality must not exceed the applicable equipment threshold at the time of replacement.

(b) Expenditures associated with activities essential to acquiring and making operational the replacement equipment shall also be exempted from review. “Activities essential to acquiring and making operational the replacement equipment" means those activities that are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) Replacement equipment shall be comparable diagnostic or therapeutic equipment in relation to the replaced equipment. “Comparable diagnostic or therapeutic equipment” means equipment which is functionally similar and which is used for the same or similar diagnostic or treatment purposes. Replacement equipment is comparable to the equipment being replaced if it is functionally similar and is used for

the same or similar diagnostic, therapeutic, or treatment purposes as the equipment currently in use and is not used to provide a new health service;

(17) new institutional health services offered by or on behalf of a Health Maintenance Organization, or a health facility controlled, directly or indirectly, by a Health Maintenance Organization or a combination of Health Maintenance Organizations, provided specific and detailed documentation is provided to the Department that one of the following conditions are met:

(a) that 75 percent of the patients who can reasonably be expected to use the service will be individuals enrolled in a Health Maintenance Organization certified by the State of Georgia;

(b) that the service is needed by the Health Maintenance Organization in order to operate efficiently and economically and that it is not otherwise readily accessible to the Health Maintenance Organization because:

1. existing similar services are not available under a contract of reasonable duration;

2. full and equal staff privileges are not available in existing facilities; or

3. arrangements with existing facilities are not administratively feasible;

(18) the addition to or replacement of computer or other information systems; and

(19) capital expenditures for a project otherwise requiring a Certificate of Need if those expenditures are for a project to remodel, renovate, replace, or any combination thereof, a medical-surgical hospital and all the following conditions are met:

(a) the hospital has a bed capacity of not more than 50 beds;

(b) the hospital is located in a county in which no other medical-surgical hospital is located;

(c) the hospital has at any time been designated as a disproportionate share hospital by the Department;

(d) the hospital has at least 45 percent of its patient revenues derived from Medicare, Medicaid, or any combination thereof, for the immediately preceding three years;

(e) the project has at least 80 percent of its capital expenditures financed by proceeds of a special purpose county sales and use tax imposed pursuant to Article 3 of Chapter 8 of Title 48;

(f) the proposed replacement hospital is located within a three-mile radius of and within the same county as the hospital's existing facility; and

(g) the project does not result in any of the following:

1. the offering of any new clinical health services;

2. any increase in bed capacity;

3. any redistribution of existing beds among existing clinical health services; and

4. any increase in the capacity of existing clinical health services.

111-2-2-.04 Periodic Reports. The availability of accurate, current data is critical for adequate health planning and for the review process. Therefore, all inpatient and outpatient health care facilities and services subject to Certificate of Need review will be required to provide complete and accurate data, in a timely manner, as required by the Department.

(1) **Annual and Special Questionnaires.**

(a) All CON-regulated facilities and services shall complete and submit certain surveys annually and periodically to the Department, as deemed necessary by the Department.

(b) Survey notices will be mailed or electronically transmitted by the Department to each such facility. The accurately and fully completed survey, covering the report period indicated, shall be filed with the Department within the time frame specific in the notice. The Survey shall be filed with the Department in the electronic format designated by the Department in the Survey Notice or on the Department's website. The survey shall include an electronic signature as authorized by law, of the chief executive officer or principal administrator of the facility, who shall attest to the accuracy and completeness of the information provided.

(c) Reporting requirements shall also apply to new health facilities and services approved through Certificate of Need review. Generally, new facilities and services will be required to report if approved for operation or occupancy for 60 days or more of the report period.

(d) Surveys submitted to the Department pursuant to these Rules and any service-specific Rules shall not be available for public review until after the deadline for submission for all surveys of that type;

(e) Required surveys submitted for a given period of time may not be revised by the facility or service after the survey filing deadline unless the request for revision is approved by the Department at its sole discretion.

(2) Post-Approval Reporting.

(a) All entities receiving a Certificate of Need shall maintain a valid and accurate mailing address with the Department. Any notification, notice, or letter required by these Rules is deemed to be received by the certificate holder when the Department mails such notification, notice, or letter to the mailing address on file with the Department.

(b) Persons holding Certificates for construction projects shall, within 12 months of the effective date of the Certificate, i.e. at the end of the implementation period, provide a progress report to the Department including documentation of the following:

1. that the construction plans have been approved by the Department;

2. that a construction contract has been signed, specifically indicating beginning and completion dates;

3. that construction materials and equipment are on the site and construction of the project has actually begun.

(c) The Department shall monitor the certificate of need holder's progress in completing the project and phases thereof, as applicable, within the effective period as specified at 111-2-2-.02(5). Each Certificate of Need issued requires a regular reporting of the different stages of development to completion. All projects approved as presented with phases shall submit a progress report within 45 days of the completion of each phase. All Certificate of Need projects must satisfy the pertinent reporting requirements or the Certificate shall be subject to revocation. These reports shall include information as to the total dollar amount of capital expenditures that have been obligated under the certificate, and any changes in amounts of proposed or previously obligated capital expenditures or changes to the timing of phases, if approved by the Department in advance. These reports will be made on a form provided by the Department on its website and will be due on the date or dates indicated by the Department on attachments to the Certificate of Need and in subsequent correspondence.

(d) The Department may also request additional reports as often as necessary in order to determine:

1. if the timetable specified in the certificate is being met;

2. if the scope of the project is being completed as described on the certificate and in the application for the certificate of need;

3. if the amount of the capital expenditure or expenditures obligated under the certificate has exceeded or can be expected to exceed the maximum under the certificate; and

4. if the condition(s) of approval, if any, have been satisfactorily met.

111-2-2-.05 Enforcement.

(1) Revocation.

(a) In the event that the Department has cause to consider revocation of a Certificate, the Department shall provide notice to the holder of the Certificate and shall hold a hearing to determine whether the holder has:

1. Intentionally provided false information to the Department;

2. Failed to incur a financial obligation in accordance with the Certificate as granted;

3. Failed to implement the project in accordance with the specific purpose(s) for which the certificate was granted or failed to meet the initial twelve-month performance standards or failed to request an extension of such standards;

4. Transferred controlling ownership in the facility before completion of the project without prior written approval of the Department, except as authorized by 111-2-2-.02(4);

5. Changed the defined location of the project except as allowed by O.C.G.A. § 31-6-45(a) authorizing change in location under certain conditions;

6. Failed to comply with any and all requirements or conditions of the Certificate; or

7. Failed to submit complete and accurate periodic reports as required by 111-2-2-.04.

(b) In the event that there is sufficient evidence to justify revocation of a Certificate, the Department shall provide written notification to the holder, which shall be effective as of the postmark date on the notification letter. Notice shall also be provided to the public, to the county or municipal authority and to the appropriate Regional Development Center. Any person whose Certificate is revoked under this rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(c) A person whose Certificate of Need has been revoked or denied may not reapply for a Certificate of Need for the same or substantially similar project for at least one hundred twenty (120) days from the date that the revocation or denial becomes final, at which time the person may submit a new application. For purposes of this subparagraph, a decision revoking or denying a Certificate of Need shall become final when the time for appealing that decision expires without an appeal of such decision having been timely filed. If an appeal is timely filed, the decision is not final until the resolution of the administrative appeal, if any.

(d) A person holding a Certificate of Need may voluntarily request revocation of the Certificate without prejudice by submitting such request to the Department in writing.

(e) A health care facility which has a certificate of need or is otherwise authorized to operate pursuant to this chapter shall have such certificates of need or authority to operate automatically revoked by operation of law without any action by the Department when that facility's permit to operate pursuant to O.C.G.A. § 31-7-4 is finally revoked by order of the Department of Human Resources. For purposes of this subsection, the date of such final revocation shall be as follows:

1. When there is no appeal of the order pursuant to O.C.G.A. § 31-5, the one hundred and eightieth day after the date upon which expires the time for appealing the revocation order without such an appeal being filed; or

2. When there is an appeal of the order pursuant to O.C.G.A. § 31-5, the date upon which expires the time to appeal the last administrative or judicial order affirming or approving the revocation or revocation order without such appeal being filed.

The Department may become a party to any judicial proceeding to review a decision by the Department of Human Resources to revoke such a permit.

(f) A certificate shall be subject to revocation for the following failures, without limitation:

1. Failure to incur a project-specific capital expenditure, within the initial 12-month implementation period specified at 111-2-2-.02(6) and in the Certificate itself or within an extension implementation period granted by the Department, through initiation of substantial project above-ground construction or lease or purchase of the proposed equipment;

2. Failure to file the required Progress Report(s);

3. Failure to meet the conditions on the face of the Certificate; or

4. Failure to pay any penalty assessed pursuant to O.C.G.A. § 31-6-40.1.

(2) **Sanctions.**

(a) Any health care facility offering a new institutional health service without having obtained a Certificate of Need and which has not been previously licensed as a health care facility shall be denied a license to operate by the Department of Human Resources.

(b) In the event that a new institutional health service is knowingly offered or developed without having obtained a Certificate of Need as required by O.C.G.A. § 31-6or by these Rules, or the Certificate of Need for such service is revoked according to the provisions of 111-2-2-.05(1), a facility or person may be fined an amount not to exceed $5,000.00 per day for every day that the violation of this these Rules and O.C.G.A. § 31-6 has existed and knowingly and willingly continues; provided however, that the expenditure or commitment of or incurring an obligation for the expenditure of funds to take or perform actions not subject to this chapter or to acquire, develop or prepare a health care facility site for which a Certificate of Need application is denied, shall not be a violation of this Chapter and shall not be subject to such a fine. The Commissioner or

his designee shall determine, after notice and a hearing if requested, whether the fines provided in the Code section shall be levied.

(c) Any person who acquires a health care facility by stock or asset purchase, merger, consolidation, or other lawful means shall notify the Department of such acquisition, the date thereof, and the names and address of the acquiring person. Such notification shall be made in writing to the Commissioner or his designee within 45 days following the acquisition and the acquiring person may be fined by the Department in the amount of $500.00 for each day that such notification is late.

(d) The Department may require that any applicant for a certificate of need commit to provide a specified amount of clinical health services to indigent or charity, Medicare, Medicaid, PeachCare, and similar patients as a condition for the grant of a Certificate of Need. A grantee or successor in interest of a Certificate of Need or authorization to operate under O.C.G.A. § 31-6 which violates such an agreement, whether made before or after July 1, 1991, shall be liable to the Department for a monetary penalty in the amount of the difference between the amount of services so agreed to be provided and the amount actually provided. Penalties authorized under this Code section shall be subject to the same notices and hearing for the levy of fines under 111-2-2-.05(2)(b).

(e) All hearings under this Section shall be in accordance with the "Georgia Administrative Procedure Act". Any person so penalized under this rule is entitled to judicial review, pursuant to O.C.G. A.§. 50-13 et seq.

(f) If the person assessed fails to pay the amount of the assessment to the Department within thirty (30) days after notice of assessment is postmarked to him, or within such longer period, not to exceed 90 days, as the Department may specify, the Department may institute a civil action to recover the amount of the assessment or may revoke the certificate of need. The Department may add reasonable interest to the assessment.

(g) For purposes of this Rule, the State of Georgia, acting by and through the Department or any other interested person, shall have standing in any court of competent jurisdiction to maintain an action for injunctive or other appropriate relief to enforce the provisions of this rule.

(3) **Department's Right to Inspect and Audit.** The Department or an authorized representative or employee designated by the Department shall have the right to inspect and audit any facility, site, location, book, document, paper, files, or other record of the holder of the certificate of need or letter of non-reviewability or other determination that is related to any project authorized by the certificate of need or letter of non-reviewability or other determination, in order to monitor and evaluate the person's compliance with the terms of issuance of the certificate of need or the letter of non-reviewability or other determination.

111-2-2-.06 Application for Certificate of Need.

(1) Contents of Application. Applications shall contain all relevant data, information and assurances required by the Department. The Department will provide application forms on request, and all applications must be on the form supplied by the Department or a copy thereof, and comply with the content requirements specified thereon. Applications shall provide information including, but not necessarily limited to, the following categories as they relate to the proposed projects:

(a) identification of the applicant;

(b) ownership;

(c) site identification;

(d) compliance with State and local codes and ordinances, including flood hazards;

(e) a detailed and complete description of proposed project;

(f) project justification, including specific documentation of the need (utilizing the Department's data and methodology) that the population to be served has for the project;

(g) staffing and operation;

(h) financial information, which shall include positive evidence of ability to obtain financing, the source of financing, and maximum interest rates, which will be paid to the lender. Applications submitted for or on behalf of a health care institution shall include one copy of the latest audit report (or internal financial statement for investor-owned facilities). Also submitted shall be all pro forma financial data requested in the application;

(i) cost containment and quality of care considerations;

(j) project design and construction schedule including as applicable

1. Schematic Design Documents meeting the standards defined by the American Institute of Architects in section 2.4.2 of the Standard AIA Contract Language. These Schematic Design Documents shall establish the conceptual design of the Project illustrating the scale and relationship of the Project components. The Schematic Design Documents shall also include a conceptual site plan, if appropriate, and preliminary building plans, sections and elevations. Preliminary selections of major building systems and construction materials shall be noted on the drawings or described in writing;

2. A written summary of the Architect’s evaluation and planning findings and recommendations meeting the standards defined by the American Institute of Architects in section 2.3 of the Standard AIA Contract Language. This summary shall include, as applicable, an evaluation of the Applicant’s program and

schedule requirements and budget for the Cost of the Work, each in terms of the other, a preliminary evaluation of the Applicant's site for the Project based on the information provided by the Applicant of site conditions, and the Applicant's program, schedule and budget for the Cost of the Work, and an evaluation of the applicant's proposed method of contracting for construction services; and

3. A detailed description of the proposed timeline and phases for project completion.

(k) a cost estimate prepared by a licensed architect or engineer within the 60 days immediately preceding submission of the application;

(l) documentation from the Office of Regulatory Services of the Department of Human Resources of no uncorrected licensure operational standards in the applicant's facility, if applicable.

(2) **Submittal of Applications.**

(a) Applicants should submit to the Department one (1) signed copy of the application plus the original. The original, signed by the applicant, must accompany the copy. Failure to provide a copy or an original signature of the legal representative of the applicant will result in non-acceptance and return of the application.

(b) Applications received after 3:00 p.m. on any business day will be considered to have been received on the next business day. Receipt of the application will be acknowledged in writing by the Department.

(3) Filing Fee Required.

(a) Each application for a Certificate of Need review shall be accompanied by a fee, except for the provisions covered in 111-2-2-.06(3)(d) and 111-2-2-.06(3)(e), the amount of which shall be determined by the following schedule:

1. for applications with a total project cost from zero to $1,000,000, the fee shall be $1,000; and

2. for applications with a total project cost greater than $1,000,000, the fee shall be one-tenth of one percent (.001) of the total cost but not to exceed $50,000; and

3. for the review of cost overruns the fee shall be computed as shown above for the amount of the overrun only.

(b) For any project, which is to be accomplished by lease, gift or other means of acquisition, the dollar value for purposes of computing the fee will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure, which would be required for purchase. The value of the facilities to be acquired is based on a current (within six months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by certified check or money order made payable to the State of Georgia and must be received by the Department before an application will be accepted for review. Failure to provide payment of the appropriate fee will result in non-acceptance and return of the application. Fee payments are collected as general State revenue.

(d) State-owned institutions shall be exempt from payment of a filing fee.

(e) The Department may waive payment of a filing fee, or any portion thereof, for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. A party requesting a waiver must make such request at the time the application is submitted to the Department.

(f) Subject to the rules in (a) through (e) above, applicants shall submit an additional filing fee for additional information or amendments provided during the review period that increase the cost of the project. For such supplementary information which increases the cost of the project, the amount that shall be submitted is an amount equal to the difference between the calculation of the filing fee based on the total amended project costs as outlined in (a) and the filing fee paid at the time of application, except that in no case shall the amount submitted be less than $500. Should such supplementary information decrease the costs associated with a project, the filing fee shall not be reduced or refunded. The Department shall not issue decisions on applications for which such supplementary information has been provided where an applicant has not submitted the additional filing fee, as applicable.

(4) Review for Completeness.

(a) Upon receipt of an application, the Department shall determine whether the application is complete. No application shall be reviewed until it has been determined by the Department to be complete in accordance with information requirements specified in this Section.

(b) An application will be determined to be incomplete if any of the following were not either provided with the application or, as may be specified in this Section, submitted previously to the Department:.

1. all the required data, information and assurances provided on the correct forms, including but not limited to the following:

(i) detailed description of the proposed project as required by 111-2-2-.06(1)(e);

(ii) financial program to meet the requirements of 111-2-2-.06(1)(h);

(iii) documentation of necessary financing for the project, such as a letter of credit, etc.;

(iv) financial pro forma to meet the requirements of 111-2-2-.06(1)(h); and

(v) most recent audited financial statements, or personal financial statements if audited statements are not available (tax returns would meet this requirement for unaudited entities and individuals);

(vi) for projects invoking service-specific Rules, as outlined in Rules 111-2-2-.20 et seq., the appropriate service-specific review considerations;

(vii) for projects involving construction, renovation, and/or expansion, schematic plans and cost estimates certified by an architect, engineer, or general contractor, as appropriate and as required by 111-2-2-.06(1)(k);

(viii) for projects involving the acquisition of equipment, purchase orders or invoices, as appropriate;

2. appropriate number of copies of the application sent to the Department, pursuant to and in compliance with 111-2-2-.06(5);

3. signatures on all copies, with an original signature of the applicant on the application determined by the applicant as the original;

4. payment of the filing fee, as described in 111-2-2-.06(3);

5. the most recent three (3) years of all required surveys, as may be previously submitted to the Department, including the Annual Hospital Questionnaire, Annual Nursing Home Questionnaire, survey of home health agencies, or other data-gathering instruments required by the Department for any health care facilities and services owned or operated by the applicant, to include data requested pursuant to O.C.G.A. § 31-6-70. In order for an application to be deemed complete, such surveys and data-gathering instruments shall be complete and accurate, as determined by the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have submitted completed questionnaires with the Department;

6. written verification certifying entitlement to any necessary real estate property or leasehold as described by the applicant in the application. Verification of entitlement shall include, but not be limited to, deeds, contracts, lease arrangements, conditional sales agreements or a comparable arrangement that purports to be a transfer of ownership in whole or in part. If an unsigned lease arrangement is submitted, the Applicant shall also submit an original letter documenting both the lessor's and lessee's commitment to participate in the lease once the CON is approved;

7. authorization to conduct business, including but not limited to, as appropriate:

(i) if the applicant is an entity requiring authorization by the Secretary of State to become a legal entity entitled to do business in the State of Georgia, such documentation;

(ii) by-laws, articles of incorporation, or articles of organization; and

(iii) if the applicant is an existing and licensed or permitted entity, a copy of such license or permit.

8. The applicant shall file one copy of the application with the office of the County Commissioner of the county in which the project exists or is proposed. The applicant shall submit with the application an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission;

9. all post-approval reporting requirements as mandated at 111-2-2-.04(2) for all previously approved projects, as may be previously submitted to the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have met the said post-approval reporting requirements for all previously approved projects with the Department;

10. the written vendor lobbyist certification required by 111-1-2-.03(2);

11. In order to be determined complete, an applicant must be current will all indigent and charity care commitments, if any, made to the Department as a condition or requirement for past approval of a project. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation are current with any and all indigent and charity care commitments made to the Department; and

12. In order to be determined complete, an applicant must be current with any and all fines, if any, levied by the Department for violation of these Rules.

(c) The Department shall notify the applicant within ten business days following receipt of the application that the application is complete as submitted or that additional information is required to complete the application. If additional information is required, the notice shall include a statement of the specific additional information required. Notice shall be effective the date it is postmarked by the Department.

(d) The Department shall notify the applicant no later than ten business days following receipt of the additional information whether such information is sufficient to complete the application. If it is not sufficient, the notice shall include a specific statement of the information which needs clarification or which does not adequately respond to the original request.

(e) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information requested on a notice of incompleteness within two calendar months after the date of the original letter notifying the applicant of the information necessary for completeness.

(f) In addition to the provisions of a paragraph (b) above, additional requirements shall be in effect where the application involves the acquisition of a hospital owned or operated by or on behalf of a political subdivision, any combination of such

subdivisions, or by or on behalf of a hospital authority. These requirements shall be as follows:

1. in the event that a health care facility, which has been assisted at any time during the past twenty years through a grant of State funds, is proposed to be acquired by a nongrant-eligible entity, the Department, in accordance with O.C.G.A. §§ 31-7-53(c) and 31-7-57(d), is required to recover the funds granted by the State. A commitment regarding return to the State of such monies consistent with the Code should be forwarded to the Department no later than the end of the review period.

2. there shall be submitted a written agreement between the parties containing the following commitments:

(i) that the purchaser or lessee will annually allocate funds for the purpose of providing indigent/charity care. The funds allocated will be no less than three percent of the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare contractual adjustments have been deducted. The funds allocated will be based on the previous year's financial records, except the first year of operation following an acquisition the three percent will be based on the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare adjustments have been deducted. For purposes of this rule; gross revenues will include all income derived from all sources;

(ii) that the purchaser will agree that no resident of the county in which the hospital resides will be denied emergency care (including emergency obstetrical care) due to inability to pay;

(iii) that the purchaser will participate in the Medicaid and Medicare programs and the State Health Benefit Plan, if authorized by the Department..

(5) Submission of Information and Documents. For the purposes of meeting any deadlines imposed by either these Rules or O.C.G.A. § 31-6, the Department will not accept any information or documents that are submitted either via telephone or facsimile. In order to meet any of the above referenced deadlines, it will be necessary to submit the information or documents either via the postal service or hand delivery, as the term hand delivery is commonly known and used. For the purposes of this rule, the use of a common carrier or a courier service shall meet the requirement of hand delivery. At all times, the interested party shall submit either the original document or a certified copy thereof. Except as otherwise provided, information and documents received after 5:00 p.m. on any business day will be considered to have been received on the next business day. Except as otherwise provided by these Rules, all documents required and described in these Rules, except for the periodic reports described in 111-2-2-.04, including, but not limited to, applications, opposition letters, supplementary information, requests for determinations, challenges to determinations, and requests for letters of non-reviewability shall be submitted with a signed original and one (1) copy.

111-2-2-.07 Review Procedures.

(1) **Beginning of Review Process.**

(a) When an application is deemed by the Department to be complete, the Department shall provide written notice to the applicant of the completeness of the application and the schedule for review. The Department shall provide similar notice to a newspaper of general circulation in the county of the project, to the appropriate Regional Development Center, and to the chief elected official of the county and municipal government, if any, within whose boundaries the proposed project would be located. The date on the letter of notification shall be deemed to be the date of notification and the beginning date of the Certificate of Need review cycle.

(b) The Department will schedule reviews so that, unless joined with another application, no review shall, except as noted in (d) below, take longer than 90 days from the date of notification of the beginning of review until the date the decision to issue or not to issue a Certificate of Need is postmarked to the applicant. Absent good cause, the Department generally will not issue a decision prior to the 60th day of the review cycle.

(c) In the event that, from the time an application is declared complete until 30 days thereafter, one or more additional applications are declared complete which involve similar projects in the same or overlapping service areas, the Department may declare that such applications will be joined with the first application for review purposes. Following such joinder, none of the subsequent applications so joined may be considered as a first application for purposes of future joinder. The Department shall notify all applicants whose applications have been joined, and shall set a new time parameter for Department actions. The 90-day final decision deadline shall run from the latest date that any one of the joined applications was declared complete for review. Except as otherwise provided, such joinder shall be the sole method of comparative review for all applications filed after July 1, 1994.

(d) Where the Department determines that conditions exist which make it impractical to complete a review in 90 days, the Department may, on notification to the applicant, extend the time limit another 30 days. Conditions, including but not limited to the following, may constitute cause for extending the time:

1. The applicant requests time to amend the application or to submit additional relevant information;

2. The Department anticipates issuance of new demographic or utilization, data affecting the application;

3. The Department has received conflicting or contradictory information necessitating further investigation;

4. Results of impending legal action may have an effect on the application.

(e) For good cause shown, as shall be determined by the Department, a public hearing will be held at a time and location specified by the Department.

1. A request for a public hearing shall be signed by at least ten residents of the area where the project is located and must be received by the Department within 20 days after the beginning date of the review cycle. The request shall include justification for the public hearing based on circumstances described in this paragraph.

2. To the extent possible, notification will be provided in a newspaper of general circulation in the area where the project is located approximately two weeks in advance of the hearing.

3. Any person desiring to offer testimony at the hearing will be given the opportunity to do so, but the providing of such testimony or evidence shall not confer upon the person or persons so testifying the status of "party" as that term is used in the Administrative Procedure Act.

4. Where distance and the nature of the project warrant, and within the budget constraints of the Department, the public hearing may be held by the Department in the area where the project is proposed to be located. Circumstances, which may indicate good cause for a hearing in the area, include but are not limited to:

(i) Projects, which could have significant effect on access to frequently used services by a sizable population group;

(ii) Projects generating strong conflicting viewpoints by the residents of an area;

(iii) Projects with potential for unusually significant impact on existing services.

5. A summary report of the hearing will be prepared, a copy of which will be sent to the party requesting the hearing and to the applicant. Such report will be made a part of the master record regarding the project. The Department may charge a fee for the summary report.

(f) Any interested person may submit information in writing to the Department concerning an application. Where information received is in opposition to the application, the Department will provide to the applicant a copy of the information and an opportunity to respond. A person wishing to file opposition with the Department must submit a separate letter of opposition for each project or application that is opposed. Opposition shall be submitted to the Department in accordance with and in compliance with 111-2-2-.06(5). Such opposition shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2). The Department shall not consider opposition statements or letters that oppose more than one project, do not have the signed vendor lobbyist certification, or do not have the appropriate number of copies as required by these Rules.

1. Letters of opposition to the original application must be received by the Department no later than the 60th day of the review period. The Department shall not consider and will not accept into the Master File any letter of opposition to the original application received after the 60th day of the review period. For applications that have been granted an expedited review by 111-2-2-.07(1)(k) or

(l), letters of opposition to the original application must be received by the Department no later than the 30th day of the review period.

2. An applicant's response(s), if any, to letter(s) of opposition to the original application must be received by the Department prior to the 75th day of the review period. The response(s) to letters of opposition to the original application may be submitted in tandem with additional information. For applications that have been granted an expedited review by 111-2-2-.07(1)(k) or (l), an applicant's response(s) to letters of opposition to the original application must be received by the Department prior to the 35th day of the review period.

3. If additional information is submitted by the applicant to the Department prior to the 75th day of the review period:

(i) any interested person may submit a letter of opposition to additional information. A letter of opposition to the additional information must be received by the Department by the 83rd day of the review period. A letter of opposition to additional information may only refer to and oppose items and information that are supplemental to the original application and which appear in the applicant's additional information; and

(ii) an applicant's response(s), if any, to letter(s) of opposition to additional information must be received by the Department prior to or on the 87th day of the review period;

4. If an amendment is submitted by an applicant no later than 10 days prior to the end of the review period:

(i) any interested person may submit a letter of opposition to the amendment. A letter of opposition to the amendment must be received by the Department no later than 5 days prior to the end of the review period; and

(ii) an applicant's response(s), if any, to letter(s) of opposition to the amendment must be received by the Department no later than 3 days prior to the end of the review period;

(g) If during the first 2 months of the review of the application the Department finds there are factors that create a potential for denial of the application, the Department shall, on or before the sixtieth day of the review period, provide the applicant an opportunity to meet with the Department. The problems with the application will be described and an opportunity offered to amend or to withdraw the application or to submit addition information. Such addition information must be submitted prior to the seventy-fifth day of the review period.

1. "Additional information" is information and data submitted in response to a direct request from the Department at the meeting afforded an applicant after the first 2 months of the review of the application or in response to issues and concerns raised by the Department in said meeting, or in the lack of such a meeting or request by the Department, information and data submitted consistent with the scope, physical location, cost, charges, service, and owners in the originally submitted application.

Additional information must be submitted to the Department prior to the 75th day of the review period;

2. "Amendment" is a revision to the additional information or application as originally submitted that is submitted to the Department no later than ten days prior to the end of the review period and that constitutes a change in scope, physical location, cost, charge, service, or owner. The following changes in an application will qualify as an amendment:

(i) A reduction or increase in the proposed physical space capacity; or

(ii) A reduction or increase in the number of proposed beds or service units (e. g. operating rooms); or

(iii) A change in the owners of the legal applicant entity, as long as the legal applicant entity remains the same; or

(iv) A reduction or increase in a proposal's capital or operating costs; or

(v) A change in site within three miles of the site proposed in the original application or within the same service area as long as the population to be served and the service area to be served is not substantially different from that originally proposed as long as the proposed change does not require the application of a new need study or different rules; or

(vi) A reduction or subtraction in the scope of the original application; or

(vii) A change in the amount of commitment to indigent or charity care, projected utilization, financial information or patient charges that do not alter the basic financing or operations of the proposed project.

(h) The Department shall be notified with either a new application or written amendment to the current completed application when there are changes in the scope, physical location, cost, charges, service or owners of the applicant entity. Any revisions that constitute a total change in or addition to the scope of an application, in the location (except for the exemption in 111-2-2-.07(1)(g)2.(v), or in the legal applicant that would require the submission of a new application. If the Department determines that the amendment constitutes a total change in either the scope, location, or legal applicant, the original application will be considered to be withdrawn and the applicant will be so notified. An application may be amended by the applicant at any time up to ten (10) days before the end of the review period. Notification of substantial amendments will be provided to the appropriate Regional Development Center and to the chief elected official of the applicable county or municipal government, if any.

(i) The Department will give special expedited consideration to emergency expenditures required solely to cope with a situation posing an immediate threat to the health and safety of patients, visitors, or staff. The General Counsel, or his designee, may, for good cause, authorize an expenditure based on a request by telephone, with written documentation to be provided later.

(j) The Department will decline to review through Certificate of Need application capital expenditures that do not reach the dollar threshold as required under the Certificate of Need program, provided the person proposing such expenditure receives from the Department a prior written authorization for the expenditure. Where a proposal is considered to meet the above exemption a letter describing the reasons for the expenditure, the cost and the anticipated date the expenditure is proposed to be made should be submitted to the Department prior to the obligation of such funds. If, in the opinion of the Department, the expenditure is consistent with those expenditures not subject to review the Department will issue a confirmation to the requestor, which shall serve as authorization for the expenditure;

(k) The Department may conduct an expedited review of applications involving either expenditures or other reviewable matters which, in the exercise of the Department's discretion, do not relate directly to either the bed capacity of a health care facility or the provision of a clinical health service and the Department may conduct an expedited review of applications for which waiver of review is expressly permitted by a service-specific rule, Rules 272-2-.20 et seq. By way of example, and without limitation, such applications which may be given an expedited review may involve replacements of health care facilities, relocations of ambulatory surgical or obstetrical facilities or diagnostic, treatment, or rehabilitation centers, the development of parking decks or medical office buildings, the renovation of physical plants of existing health care facilities, the establishment of special care units, and the construction, development, establishment, or expansion of personal care homes.

1. Upon request, the Department will provide an expedited review request form. The Department will consider a request for an expedited review when the applicable form has been completed by the applicant and submitted to the Department.

2. No later than 14 calendar days after the date that the application has been deemed complete for review pursuant to Rule 111-2-2-.06(4), the Department will notify the applicant in writing as to whether the application will be reviewed on an expedited basis.

3. In the event that the Department decides to review the application on an expedited basis, the projected decision due date will be no later than 45 calendar days after the application has been deemed complete for review. However, the Department's failure to issue a decision on the application by the 45th calendar day of the review period shall neither result in automatic approval of the application nor prohibit the Department from issuing a decision before the 90th calendar day of the review period.

4. If during the course of the Department's review of the application the Department finds that there are factors that create a potential for denial of the application, the Department will immediately discontinue its expedited review, notify the applicant in writing of that decision, and review the application in accordance with the applicable non-expedited review procedures set forth in Rule 111-2-2-.07.

5. If within the first 30 calendar days after the application is deemed complete, an additional application is received and deemed complete by the Department which involves a similar project subject to the same Department Rules in the same or

overlapping service areas and the Department determines that such application should be joined with the first application for review, the Department will immediately discontinue its expedited review, notify the first applicant in writing of that decision, and review the applications in accordance with the applicable non-expedited review procedures set forth in Rule 111-2-2-.07.

(l) Furthermore, and consistent with the standards of (k) above, the Department shall conduct an expedited review with a review period of no longer than forty-five days only for those projects involving the following:

1. The construction of new parking decks;

2. The construction of additional spaces to existing parking decks;

3. The renovation of the physical infrastructure of health care facilities if the cost is over the Department's capital expenditure threshold, and thus not eligible for the express exclusion of 111-2-2-.03(12); the space to be renovated must not include any areas devoted to the provision of a clinical health service;

4. The construction of new medical office buildings if no clinical health services are to be offered in such buildings;

5. The addition of new space to existing medical office buildings if no clinical health services are offered in the existing building, and the new construction will not involve the offering of clinical health services in the building;

6. The expansion of an adult open heart service based solely on an increase in procedures as defined in 111-2-2-.22(2)(d), provided that the application for expansion is submitted pursuant to the provisions of 111-2-2-.22(3)(b)2.

7. The Department shall issue a decision on applications for a Certificate of Need for the type of projects outlined above no later than forty-five (45) days after the application has been deemed complete for review; failure to issue the decision on or before the forty-fifth (45^{th}) day after it has been deemed complete for review shall result in an automatic approval of the application, subject to subsection (8) below; the decision issued by the Department shall be a summary statement of the findings during the review of the project;

8. If, during the course of the review period, the Department finds that there are factors that create the potential for denial of the application, the Department shall immediately discontinue its expedited review, notify the applicant in writing of that decision, and review the application in accordance with the applicable non-expedited review procedures set forth in Rule 111-2-2-.07.

9. The review of such projects as outlined in sections 1. through 8. above shall be governed by the provisions of this subsection and not the provisions of subsection (k) above.

10. The filing fee for applications of the type specifically listed in subsection (l)(1-6) above shall be $1,000.00, notwithstanding the filing fee provisions of Rule 111-2-2-.06(3)(a).

(2) **Department Review.**

(a) In reviewing the application, the Department will take into consideration the review considerations and policies provided in 111-2-2-.09. The latest applicable data from official data sources will be used in the Department analysis, unless otherwise provided by a service-specific rule. Such data sources will include, but not be limited to, the State Office of Planning and Budget, Medicare/Medicaid Cost Reports, and questionnaires or surveys initiated by the Department.

(b) Upon completion of review, the Department shall provide written notification of its decision to issue or deny a Certificate of Need. In the event of a favorable decision, the letter shall serve as the Certificate.

1. Such decision will be postmarked no later than 90 days from the beginning of the review period unless the total review period is extended in accordance with 111-2-2-.07(1)(d).

2. The date of the decision shall be the date on the notification letter of the Department.

(c) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need;

2. Information pertaining to the availability of an appeal hearing.

(d) The decision shall be to approve or deny the application as submitted or as amended by the applicant during the course of review.

(e) A copy of the notification will be sent to the applicant or, in the case of joined applications, to all applicants, to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. A copy may be made available to other interested persons on request.

(f) Should the Department fail to issue a decision letter on a Certificate of Need application within the time limits set forth in these Rules, the application shall be deemed approved as of the ninety-first day, or the one hundred twenty-first day if the review period was extended pursuant to 111-2-2-.07(1)(d), following the date of notice from the Department that an application, or the last of any applications joined pursuant to 111-2-2-.07(1)(c) was declared complete for review.

(g) Appeals of the decision of the Department shall be processed in accordance with rules promulgated by the Health Planning Review Board found in Chapter 274.

(h) When a project undergoes judicial review, the Department may stay the effective date of the CON pending the outcome of the judicial review upon appropriate terms for good cause shown.

111-2-2-.08 Alternative Application and Review Procedures.

(1) Batching Review Process.

(a) Pursuant to O.C.G.A. § 31-6-40.1(b), the Department may limit the time periods during which it will accept applications for the following health care facilities and/or services: skilled nursing facilities; intermediate care facilities; and home health agencies. Limitation of the time periods shall be to only such times after the Department has determined there is an unmet need for such facilities and/or services. The Department shall make a determination as to whether or not there is an unmet need for each type of facility at least every six months and shall notify those requesting such notification of that determination. No application for skilled nursing facilities, intermediate care facilities, or home health agencies will be accepted for review by the Department except as provided for pursuant to Rule 111-2-2-.08(1). For purposes of batching only, the applications entered into the one hundred twenty (120) day review period shall be evaluated according to the data used to publish the unmet need for the particular service at issue, either home health services or nursing facility services, and not the latest available data at the time of decision, as is the case with all non-batched applications.

(b) Upon the determination of an unmet need for a particular facility/service in a given service area, the Department shall provide notice indicating which applications will be considered in that particular batching cycle to all interested parties requesting notice of that determination. It shall be the sole and exclusive responsibility of the interested party to notify the Department in writing of that party's desire to be informed of the Department's unmet need determination(s) for batching purposes. The Department's notice shall contain the unmet need for the type of facility/service in the given service area(s) and shall also contain the pertinent time frames and deadlines for submission of notices of intent to apply, for submission of applications, and the review of such applications.

(c) All parties interested in applying for the particular unmet need in a given service area must notify the Department of that party's intent to apply.

1. The notice must be in writing and must address specifically the type of unmet need and service area(s) for which the applicant intends to apply.

2. The notice of intent must be received by the Department no later than the close of business on the thirtieth (30th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the thirtieth (30th) calendar day falls on either a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday.

3. Notwithstanding any other relevant provisions within this rule, the notice of intent to apply must be received by the Department either before or simultaneously with the submission of the actual application in accordance with the notice of intent deadline.

4. In the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party shall be disqualified automatically from applying during that batching cycle.

(d) Subject to the proper submission of a notice of intent to apply, any interested party shall have in the Department's office a properly submitted application no later than 12:00 P.M. on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. For purposes of batching only, all properly submitted applications will be deemed received on the sixtieth (60th) day, regardless of the actual date of submission.

(e) For the purposes of batching only, an application which has been deemed received according to (d) above, will be only be deemed properly submitted and complete if the following requirements, in addition to the requirements of 111-2-2-.06(4), are met:

1. The appropriate Certification Statement (either a "Nursing Home Completeness Checklist" or a "Home Health Department Checklist") is submitted simultaneously with the original application; and

2. All of the items addressed in the Certification Statement are provided, as certified, with the original application.

(f) In the event that an application is deemed in receipt by (d) above, but is not deemed to be properly submitted and complete by (e) above by 12:00 PM on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need (in the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday), the application will be disqualified from the batching review.

(g) The batching review cycle will be conducted in the following manner:

1. The batching review cycle shall be one hundred and twenty (120) days in duration. As a result, no party participating in the batching review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day.

2. The first day of the batching review cycle shall be the day upon which all properly submitted applications are deemed to be received. [See Rule 111-2-2-.08(1)(d) above.]

3. On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth (75th) day of the batching review cycle.

4. The last day for interested parties (including, but not limited to, competing applicant(s) and/or existing competing health care facilities) to submit letters of support or opposition addressing the underlying merits, or lack thereof, including any specific reasons for the opposition, of any pending application/s shall be the eighty-fifth (85th) day of the batching review cycle. Any letters of support and/or opposition that are received after the eighty-fifth (85th) day of the batching review cycle shall not be considered by the Department in its review of the pertinent application(s) and the letter(s) shall not become part of the master file compiled for the pertinent application(s). Letters of support and letters of opposition must pertain to only one application and one applicant. In no case shall the Department accept a letter of opposition or support that concerns multiple applicants or applications. Letters of opposition must be submitted pursuant to and in compliance with 111-2-2-.06(5). Such requests shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).

5. Applicants shall be given the opportunity to respond to letters of opposition. The last day for the applicant(s) to submit final amendments and responses to letters of opposition shall be the one hundred and tenth (110th) day of the batching review cycle.

6. No later than the one hundred and twentieth (120th) day of the batching review cycle, the Department shall provide written notification of its decision to issue or deny a Certificate of Need to the pertinent applicant(s).

(h) In evaluating batched applications, if any or all of the batched applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. The past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. Specific services to be offered;

3. Appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. Demonstrated readiness to implement the project, including commitment of financing;

5. Patterns of past performance, if any, of the applicants in implementing previously approved projects in a timely fashion;

6. Past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. Evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and

8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.

(i) In the event of a favorable decision, the Department's notification letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter of the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the batching review cycle, whichever is applicable. The effective date of the Certificate shall be the decision or approval date if not appealed. If administratively appealed in a timely fashion, the effective date of the Certificate shall be the date of final resolution of any administrative hearing. The Department may stay the effective date of a project appealed through judicial process at the request of any party to such appeal or upon the Department's own initiative. Any determination by the Department to stay the effective date will be based upon sound health planning principles. If the Department stays the effective date of a project appealed through judicial process, the effective date shall be the date of final resolution of any judicial appeal.

(j) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

2. Information pertaining to the availability of an appeal hearing.

(k) A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

(l) Appeals of the Decision of the Department shall be in accordance with the Rules promulgated by the State Health Planning Review Board found in Chapter 274.

(2) **Alternative Healthcare Models.**

(a) **Applicability.**

1. For Certificate of Need (CON) purposes, Alternative Healthcare Models are defined as new and/or innovative models of providing new or existing institutional health services delivered in a proposed or existing healthcare facility.

2. For Certificate of Need purposes, the applicant for an Alternative Healthcare Model CON will be as follows:

(i) If the service(s) will be provided within a single healthcare facility, the owner of that facility will be the applicant;

(ii) If the service(s) will be provided within two or more healthcare facilities that are part of a healthcare services network, the owner(s) of the facility(ies) in which the service(s) will be provided will be the co-applicant(s).

3. The Department shall evaluate the performance of the Alternative Healthcare Model according to the scope as defined by the Department decision and the standards set forth in these Rules. If after a review the Department determines that the Alternative Healthcare Model does not meet the defined scope or expected standards, the Department may either immediately revoke the Certificate of Need or grant a specified time period during which the Alternative Healthcare Model must meet the defined scope and the expected standards or lose its Certificate of Need.

(b) **Definitions.**

1. "Alternative healthcare model" means a new and/or innovative model of providing new or existing institutional health service(s) delivered in or through a healthcare facility(ies) and/or healthcare services networks.

2. "Authorized service" means a Department sanctioned Alternative Healthcare Model, which is either existing or approved. An existing service is an authorized service, which has become operational, and an approved service is an authorized service, which has not yet become operational.

3. "Healthcare facility" means hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes of at least 25 beds; ambulatory surgical or obstetrical facilities; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitation centers, but only to the extent that Rule 111-2-2-.01(33)(h) or (i) is applicable thereto; and facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for 24 hours or longer for persons who have traumatic brain injury, as defined in code section 37-3-1.

4. "Healthcare services network" means a collaborative arrangement that consists of at least one healthcare facility plus one or more physician groups and/or one or more third party payers, or a collaborative arrangement that includes at least two or more healthcare facilities.

5. "Most recent year" means the most recent calendar year prior to submission of an application.

6. "Official inventory" means the inventory of all authorized Alternative Healthcare Models maintained by the Department based on CON approval and official Department records.

7. "Official state component plan" means the most recent document(s) that is/are most closely related to those services being provided by the Alternative Healthcare Model. The most recent document(s) will have been developed by the Department and approved by the Health Strategies Council.

8. "State health policies" means the most recent policies developed by the Health Strategies Council, which provide a framework for the service-specific policies included within each component of the State Health Plan. These state health policies include health promotion, financial accessibility, least restrictive care, regionalization, cost containment, health planning and citizen participation, healthcare personnel, and healthcare data and information networks.

(c) **Requests for Proposals.**

1. Within the period of April 1 through May 31 of each year, the Health Strategies Council may accept abstracts describing potential Alternative Healthcare Models, based on the recommendation of the Department. The Council will review these abstracts, if any are solicited for that year, by August 31 of that year and select a list of those categories for which Alternative Healthcare Model Certificate of Need applications may be submitted.

2. Within 30 days of the determination by the Health Strategies Council of the particular categories under which Alternative Healthcare Model Certificate of Need applications may be submitted, the Department shall provide notice of these categories to all interested parties. The notice shall contain:

(i) the listing of category (ies) related goals and desired outcomes and the probable scope of services;

(ii) the pertinent time frames and deadlines for submission of notices of intent to apply for Alternative Healthcare Model Certificate of Need;

(iii) the pertinent time frames and deadlines for submission of CON applications; and

(iv) the pertinent time frames and deadlines for the review of such applications, and any related criteria for review.

(d) **Intent to Apply.**

1. All parties wanting to apply for Alternative Healthcare Model Certificates of Need under the selected categories must notify the Department of that party's intent to apply.

2. This notice must be:

(i) in writing and must address specifically the particular category under which the applicant intends to apply;

(ii) received by the Department no later than the close of business on the sixtieth (60th) calendar day following the date that the Department publishes the notice of the selected categories. In the event that the sixtieth calendar day falls on either a weekend or a legal holiday, the sixtieth calendar day shall become

automatically the next business day that is neither a weekend nor a legal holiday;

(iii) must be received by the Department either before or simultaneously with the submission of the actual application; and

(iv) in the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party automatically shall be disqualified from applying during that particular review cycle.

(e) **Application Process.**

1. Certificate of Need applications pertaining to the selected categories will be submitted to the Department on or before 3:00 p.m. June 1 of the year following the year in which the categories were selected by the Health Strategies Council. (Although applications may be submitted prior to 3:00 p.m. June 1, all application will be deemed received on June 1.) In the event that June 1 falls either on a weekend or a legal holiday, the day of submission shall become automatically the next business day that is neither a weekend nor a legal holiday;

2. Alternative Healthcare Model Certificate of Need applications must comply with the requirements in Rule 111-2-2-.06(2) and (3).

3. For the purposes of Alternative Healthcare Model Certificate of Need applications, an application will be deemed properly submitted if the following requirements are met:

(i) a summary of the Certificate of Need application is included to be used as information for the Health Strategies Council and general public;

(ii) a Certification Statement of Completeness is included designating under which category the application is being submitted; and

(iii) all items addressed in the Certification Statement of Completeness are provided with the application.

(f) **The Review Cycle.**

1. The review cycle shall be automatically one hundred and twenty (120) days in duration. As a result, no party participating in the review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day;

2. The first day of the review cycle shall be the day upon which all properly submitted applications are deemed to be received as specified in Rule 111-2-2-.08(2)(e)3.

3. No later than the thirtieth (30th) day of the review cycle, the Department shall, if deemed necessary, submit a written request to any and all pertinent applicants for

clarifying and/or supplemental information. This written request may be distributed within a meeting of the applicant(s). The purpose of the request for clarifying and/or supplemental information shall be to obtain information from the applicant(s) that clarifies or supplements the initial information submitted with the original application.

4. No later than the forty-fifth (45th) day of the review cycle, the applicant(s) shall, if deemed necessary by the Department, submit their clarifying and/or supplemental information. Failure to submit the required clarifying and/or supplemental information by the 45th day may be grounds for denial of the application.

5. If, by the 45th day, the review indicates potential for denial of the application(s), the Department, on or before the sixtieth (60th) day of the review cycle, shall provide the applicant(s) an opportunity to meet with the Department. The problems with the application(s) will be described and an opportunity offered to amend or withdraw the application or to submit additional information. Any and all additional information and amendments must be submitted on or before the seventy-fifth (75th) day of the review cycle.

6. The last day for interested parties (including, but not limited to, competing applicant(s) and/or existing competing health care facilities) to submit letters of support or opposition addressing the underlying merits, or lack thereof, of any pending application(s) shall be the eighty-fifth (85th) day of the review cycle. Any letters of support and/or opposition that are received after the eighty-fifth day of the review cycle shall not be considered by the Department in its review of the pertinent application(s) and the letter(s) shall not become part of the master file compiled for the pertinent application(s).

7. The last day for applicant(s) to submit final amendments and responses to letters of opposition shall be the 110th day of the review cycle.

8. No later than the one hundred and twentieth (120th) day of the review cycle, the Department shall provide a written letter notifying the applicant of their decision to issue or deny a Certificate of Need to the pertinent applicant(s).

9. In the event of a favorable decision, this letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter from the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the review cycle, whichever is applicable.

10. The decision letter shall contain at least the following:

(i) a detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

(ii) information pertaining to the availability of an appeal hearing.

11. A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the

applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

12. Appeals of the decision of the Department shall be in accordance with the Rules promulgated by the State Health Planning Review Board.

(g) **Standards.**

1. An Alternative Healthcare Model must be consistent with the State Health Policies adopted by the Health Strategies Council of the State of Georgia.

2. An Alternative Healthcare Model must clearly define its target population/community.

3. An Alternative Healthcare Model must:

(i) include a hypothesis(es) to be tested within a time-limited period not to exceed five years;

(ii) demonstrate, as applicable, how it will support research, new service development, health professional education and training, and/or affiliation with an academic center of higher learning; and

(iii) demonstrate that the community supports the Alternative Healthcare Model.

4. An applicant for an Alternative Healthcare Model CON shall demonstrate the feasibility of operating the Alternative Healthcare Model in Georgia, based on a review of the experience in other states including the impact on health professionals of other healthcare programs or facilities and how the project is impacted by payers and regulatory entities.

5. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to reduce healthcare costs to consumers, third party payors and the system as a whole.

6. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to maintain or improve the standards of healthcare quality in some measurable fashion.

7. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to provide increased choices or access for consumers to a continuum of services within the target community.

8. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to meet existing or emerging health status and/or health system needs.

9. For any applicant that meets the requirements of this rule the Department may waive all or part of otherwise applicable service-specific Rules 111-2-2-.20 et seq.

111-2-2-.09 General Review Considerations.

(1) **General Considerations.** The burden of proof for producing information and evidence that an application is consistent with the applicable considerations and review policies, which follow, shall be on the applicant. In conducting review and making findings for Certificates of Need, the Department will consider whether:

(a) the proposed new institutional health services is reasonably consistent with the relevant general goals and objectives of the State Health Plan. The goals and objectives related to issues and addressed in the State Health Plan, which are relevant to the Certificate of Need proposal, will be considered in the review. It should be recognized that the goals of the State Health Plan express the ideal and in some respects may be incompatible with the concept of cost containment. The statutes and Rules represent the final authority for review decisions and the content of the Plan or any component thereof shall not supersede the Rules in such determination;

(b) the population residing in the area served, or to be served, by the new institutional health service has a need for such services;

1. Population projections used by the Department will be resident population figures prepared or approved by the Office of Planning and Budget or other official figures that may be applicable as determined by the Department.

2. Updated resident population projections will be utilized upon the official effective date as stated by the Department, pursuant to these Rules, replacing and superseding the older data.

3. The projection period or horizon year for need determinations will be five years for hospital services and three years for all other services, unless otherwise provided by the Rules for the specified service. The projection period or horizon year will be advanced to the next projection year or horizon year on or about April 1 of each year.

4. Inpatient facilities will be inventoried on the basis of bed capacity approved, grandfathered, or authorized through the certificate of need process regardless of the number of beds in operation at any given time or which may be licensed by the Office of Regulatory Services, Department of Human Resources.

5. Data sources to be utilized by the Department to evaluate need, population characteristics, referral patterns, seasonal variations, utilization patterns, financial feasibility, and future trends will include, but not be limited to, the following:

(i) any surveys required by the Department, including but not limited to those for hospitals, nursing facilities, home health agencies, specialized services, and ambulatory surgery facilities;

(ii) Cost reports submitted to fiscal intermediaries and the Department;

(iii) periodic special studies or surveys, as produced or formally adopted or used by the Department;

(iv) the United States Census and other studies conducted by the Census and other Federal and State agencies and bureaus, including but not limited to, the Department of Labor; and

(v) such other data sources utilized by the Department for measurement of community health status. Such data may include information submitted by the applicant pursuant to 111-2-2-.06(1)(f), which may be necessary for the Department to ensure that the project is consistent with applicable general consideration provisions.

6. All data used by the Department in a Certificate of Need review will be available to the applicant on request, in accordance with Department policies on requested information. The most recent data reported and validated will be used in the analysis of a proposal.

(c) existing alternatives for providing services in the service area the same as the new institutional health service proposed are neither currently available, implemented, similarly utilized, nor capable of providing a less costly alternative, or no Certificate of Need to provide such alternative services has been issued by the Department and is currently valid

1. The Department supports the concept of regionalization of those services for which a service-specific rule exists.

2. The Department shall consider economies of scale where need exists for additional services or facilities.

3. Utilization of existing facilities and services similar to a proposal to initiate services shall be evaluated to assure that unnecessary duplication of services is avoided. Where there exists significant unused capacity, initiating a similar service in another health care facility would require strong justification under other criteria.

(d) the project can be financed adequately and is in the immediate and long term, financially feasible;

(e) the effects of the new institutional health service on payors for health services, including governmental payors, are reasonable;

(f) the costs and methods of a proposed construction project, including the costs and methods of energy provision and conservation, are reasonable and adequate for quality health care. Construction plans will be reviewed in detail to assure that space is designed economically. Space shelled-in for some future use will not be accepted unless the applicant demonstrates that the shelled-in space will not be directly related to the provision of any clinical health service;

(g) the new institutional health service proposed is reasonably financially and physically accessible to the residents of the proposed service area and will not discriminate by virtue of race, age, sex, handicap, color, creed or ethnic affiliation;

1. In accordance with the provision found in O.C.G.A. § 31-6-42(7), the Department will evaluate the extent to which each applicant applying for a Certificate of Need participates in a reasonable share of the total community burden of care for those unable to pay. This provision shall not apply to applicants for continuing care retirement communities, skilled nursing facilities or units, and to projects that are reviewed by the Department on an expedited basis in accordance with 111-2-2-.07(1)(l). In all other instances, the following indicators will be evaluated:

(i) administrative policies and directives related to acceptance of indigent, medically indigent, and Medicaid patients;

(ii) policies relating medical staff privileges, if applicable, to reasonable acceptance of emergency referrals of Medicaid and PeachCare patients and all other patients who are unable to pay all or a portion of the cost of care;

(iii) evidence of specific informational efforts targeted toward patients regarding arrangements for satisfying charges;

(iv) documented records of refunds, if any, received from the Federal, State, county, city, philanthropic agencies, donations, and any other source of funds other than from direct operations, such as indigent care trust fund distributions and disproportionate share payments, if applicable;

(v) the applicant's commitment to participate in the Medicare/Medicaid and PeachCare programs; to provide legitimate emergency care, if applicable, regardless of ability to pay; and to provide indigent and charity care;

(vi) documented records of care provided to patients unable to pay, Medicare and Medicaid contractual adjustment, Hill-Burton payments (if applicable), other indigent care, and other itemized deductions from revenue including bad debt. Such records shall demonstrate that the levels of care provided correspond to a reasonable proportion of those persons who are medically or financially indigent and those who are eligible for Medicare or Medicaid within the service area.

2. The evaluation in 1. above is in addition to satisfaction of a minimum indigent and charity care commitment required by prior CON(s), if any.

(h) the proposed new institutional health service has a positive relationship to the existing health care delivery system in the service area;

(i) the proposed new institutional health service encourages more efficient utilization of the health care facility proposing such service;

(j) the proposed new institutional health service provides, or would provide a substantial portion of its services to individuals not residing in its defined service area or the adjacent service area;

(k) the proposed new institutional health service conducts biomedical or behavioral research projects or new service development that is designed to meet a national, regional, or statewide need;

(l) the proposed new institutional health service meets the clinical needs of health professional training programs;

(m) the proposed new institutional health service fosters improvements or innovations in the financing or delivery of health services; promotes health care quality assurance or cost effectiveness; or fosters competition that is shown to result in lower patient costs without a significant deterioration in the quality of care; and

(n) the proposed new institutional health service fosters the special needs and circumstances of Health Maintenance Organizations.

(2) **Osteopathic Considerations.** When an application is made for a Certificate of Need to develop or offer a new institutional health service or health care facility for osteopathic medicine, the need for such facility shall be determined on the basis of the need and availability in the community for osteopathic services and facilities. Nothing in this Chapter shall, however, be construed as recognizing any distinction between allopathic and osteopathic medicine.

(3) **Minority-Administered Hospital Considerations.** If the denial of an application for a Certificate of Need for a new institutional health service proposed to be offered or developed by a minority-administered hospital serving a socially and economically disadvantaged minority population in an urban setting, or by a minority-administered hospital utilized for the training of minority medical practitioners, would adversely impact upon the facility and population served by said facility, the special needs of such hospital facility and the population to be served by said facility for the new institutional health service shall be given extraordinary consideration by the Department in making its determination of need. The term "minority-administered" means a hospital controlled or operated by a governing body or administrative staff composed predominantly of members of a minority race. The Department shall have the authority to vary or modify strict adherence to the provisions of Code Chapter 31-6-42(c) and this Chapter in considering the special needs of said facility and its population served and to avoid an adverse impact on the facility and the population served thereby.

(4) **Considerations for Joined Applications.**

(a) In evaluating joined applications, if the services proposed are found to be needed, and if both applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. the past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. specific services to be offered;

3. appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. demonstrated readiness to implement the project, including commitment of financing;

5. patterns of past performance, if any, of the applicants in implementing previously approved projects in timely fashion;

6. past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and

8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.

111-2-2-.10 Determinations and Letters of Non-Reviewability.

(1) **General Provisions Relating to Determinations and Letters of Non-Reviewability**

(a) Determinations and Letters of Non-Reviewability are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination or letter of non-reviewability, as applicable. Therefore, the conclusions of a specific determination or letter of non-reviewability shall have no binding precedent in relation to parties not subject to the request and to other facts or factual situations that are not presented in the request.

(b) This rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need.

(c) A person requesting a determination or letter of non-reviewability shall make such a request in writing and shall specify in detail all relevant facts, which relate to the proposed action or course of conduct. The request shall be directed to the General Counsel or his designee. The General Counsel or his designee shall respond to the request in writing. The request shall include, at a minimum, the following components:

1. a statement citing by appropriate reference the statutory provision or other authority under which the is to be granted by the Department.

2. the exact legal name of each person whose rights are affected and who is requesting a determination or letter of non-reviewability and the address or principal place of business of each such person. A request may be submitted by an attorney or other party on behalf of such person, but the request must include the information required by this subsection relating to the person whose rights are affected;

3. The name, title, address, telephone number, facsimile telephone number and electronic mail address of the attorney or other person, if any, to whom correspondence or communications in regard to the request shall be addressed; and

4. An explanation of any unusual circumstances involved in the request which the Department will be expected to direct its particular attention, including the existence of emergency conditions.

(d) Requests for determination or letter of non-reviewability shall address only one matter per request.

(e) Requests for determination or letter of non-reviewability shall be submitted pursuant to and in compliance with 111-2-2-.06(5). Such requests shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).

(f) Requests for determination or letter of non-reviewability shall include payment of a request fee. Payment of the fee shall be by certified check or money order made payable to the State of Georgia Department of Community Health and must be received by the Department before a determination request will be reviewed. Failure to provide payment of the appropriate fee will result in non-acceptance and return of the request.

1. The request fee for determination shall be $250.00;

2. The request fee for letters of non-reviewability shall be $500.00;

3. State-owned institutions shall be exempt from payment of these fees; and

4. The Department may waive payment of these fees for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. Such requests for waiver must be received at the time of the initial request.

(2) **Letters of Determination.** Pursuant to O.C.G.A. § 31-6-47(c), if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department rule or statutory provision upon that person's proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

(a)No person shall be entitled to request a determination that relates to an actual or proposed action or course of conduct which has been taken or which would be taken by a third party.; and

(b) In addition to the requirements of 111-2-2-.10(1), a determination request shall include a concise and explicit iteration of the facts on which the Department is expected to rely in granting the determination.

(3) **Requests for Letters of Non-Reviewability for Below Threshold Diagnostic or Therapeutic Equipment.** In addition to the requirements of 111-2-2-.10(1) and pursuant to the meaning of threshold as defined at 111-2-2-.01(44), the Department applies the following rules as they concern requests for determinations that the value of certain diagnostic or therapeutic equipment does not exceed the Department's equipment threshold, pursuant to O.C.G.A. § 31-6-2(14)(F), (H), or (F) and (H) and therefore that such equipment is not subject to prior CON review and approval.

(a) The party who requests the letter of non-reviewability must submit a manufacturer's or vendor's price quotation or purchase order for the diagnostic or therapeutic equipment. This requirement applies even if the equipment is to be leased.

(b)The party who requests the letter of non-reviewability must submit a sworn affidavit affirmed by a person capable of making a binding commitment on behalf of the manufacturer or vendor of the diagnostic or therapeutic equipment for which a determination containing the following affirmations:

1. that the affiant is capable of making a binding commitment on behalf of the manufacturer or vendor; and

2. that the price shown on the price quotation or purchase order is the total expense the requesting party is incurring for the equipment shown and the total dollar amount that the manufacturer or vendor is receiving for the exact unit shown on the quotation or purchase order; or

3. In the case of a lease or other means of acquisition, that the price shown is the total dollar amount that would have been expended had the equipment been purchased.

(c) A party requesting a letter of non-reviewability for the purchase of diagnostic or therapeutic equipment with a value below the equipment threshold must submit with the request a sworn affidavit from a person capable of making a binding commitment on behalf of the party containing the following affirmations:

1. that the affiant is capable of making a binding commitment on behalf of the party;

2. that no acquisition of additional items not listed on a Line Item Valuation Sheets or the Aggregate Valuation Sheet, to be added to or used with the operational configuration of the particular diagnostic or therapeutic equipment at issue to include functionally related equipment, will be made or will take place for a period of six (6) months from the date of installation of the equipment that would put the total expenditure incurred on the diagnostic or therapeutic equipment or its operational configuration over the Department's equipment threshold;

3. that no acquisition of additional equipment reasonably related to or associated with the general type of service provided by the equipment to be acquired not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet will occur within a period of six (6) months, that is that such expenditure for associated, but not functionally related equipment, regardless of modality, shall occur simultaneously;

4. that no construction not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet that can reasonably be determined to be associated with the equipment to be acquired will occur within a period of six (6) months;

5. that the Line Item Valuation Sheets and the Aggregate Valuation Sheet included in the request are accurate, reflect all of the expenses required by Rule 111-2-2-.10(3), and reflects the true cost of acquiring the exact same equipment and any and all associated and simultaneous items and activities; and

6. that the price shown on the price quotation(s) or purchase order(s) reflects the exact amount of the total expense that will be incurred and paid to the manufacturer or vendor for the exact same equipment listed on the price quotation or purchase order; or

7. in the case of a lease or other acquisition, that the price shown on the purchase order(s) or quote(s) is the total dollar amount that would have been expended had the equipment been purchased.

(d) The request for a letter of non-reviewability must include a, Equipment Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts

attributable to each category listed below of items the Department will evaluate for purposes of determining if the value of the diagnostic or therapeutic equipment is below the equipment threshold dollar amount. If an item is not applicable, the requesting party should include the item on the Line Item Valuation Sheet and indicate the dollar amount as $0. For each simultaneous and associated unit of equipment, as outlined at 111-2-2-.10(3)(j) below, a separate line item valuation sheet must be submitted.

1. The dollar amount of the base price of the unit before adding any of the following items;

2. Any expense incurred for the purchase of a first year's warranty on the diagnostic or therapeutic equipment from the manufacturer or vendor;

3. Any expense incurred for operator training;

4. Any expense incurred for installation and assembly of the equipment;

5. Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

6. Any expense incurred for functionally related diagnostic or therapeutic equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.

7. Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

8. Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

9. Any dollar amount attributable to service contracts for the initial year of operation;

10. Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of non-reviewability by the manufacturer or vendor of the equipment;

11. For mobile equipment, any expense incurred for a mobile coach, trailer, or van in which the equipment will be operated; and

12. The final line of the Line Item Valuation Sheet should reflect the total of the preceding eleven items.

(e) 1. The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Functional Build-Out/Finish Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to build-out to make the equipment functional to include, but not to be limited to, electrical and plumbing work to be performed, masonry expenses to lay a concrete pad, and construction of modular buildings. Each item of build-out shall be delineated. If functional build-out will not be necessary, i.e. because equipment was previously used in the exact same space, the requesting party should include the

Functional Build-Out/Finish Line Item Valuation Sheet and indicate that no functional build-out is required.

2. The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to finishing and build-out items, activities, and expenditures, if such items are associated and simultaneously developed or proposed, including, but not limited to, clinical office space, administrative areas, waiting rooms, etc. If there will be no associated and simultaneous build-out/finish, the requesting party should include the Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet and indicate that no associated and simultaneous build-out/finish is required.

(f) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate Furnishings Line Item Valuation Sheet, generated by the party requesting a letter. Pursuant to the definition of "associate with and simultaneously developed or proposed," the Furnishings Line Item Valuation Sheet should include a description of each item of furniture, the quantity of each item, a price per item, and a total based on the quantity multiplied by the price. A grand total should be calculated at the bottom of the Sheet. If no associated with and simultaneously developed or proposed expenditures related to furnishings will be incurred within 6 months of the operation of the equipment, submit a sheet entitled "Furnishings Line Item Valuation Sheet" and indicate that no furnishings will be acquired;

1. if items of furnishings are to be leased, the current market value of the furnishings shall be listed;

2. submit price quotes as applicable; and

3. both moveable and fixed furnishings shall be included;

(g) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include a separate New Construction Line Item Valuation Sheet, generated by the party requesting a letter, listing all costs attributable to associated with and simultaneously developed or proposed new construction, including, but not limited to vaults, office space and waiting rooms. If the facility under construction will be leased, the cost of the new construction for the share of the building to be occupied by the facility or service, inclusive of a share of any common spaces, shall be included. Also, any costs associated with renovation of existing space shall be included. Each item of construction shall be delineated. If new construction will not be necessary or will not be associated with and simultaneously developed or proposed, the requesting party should include the New Construction Line Item Valuation Sheet and indicate that no construction is required;

(h) The request for a letter of non-reviewability for diagnostic or therapeutic equipment must include an Aggregate Valuation Sheet, generated by the party requesting a letter, listing the following items and totals:

1. The Total of each Equipment Line Item Valuation Sheet;

2. The Total of the Functional Build-Out/Finish Line Item Valuation Sheet;

3. The Total of the Associated and Simultaneous Build-Out/Finish Line Item Valuation Sheet;

4. The Total of the Furnishings Line Item Valuation Sheet;

5. The Total of the New Construction Line Item Valuation Sheet; and

6. The grand total of the previous five items.

(i) A party adding an item, or incurring an expense of the types listed in 111-2-2-.10(3)(d) through (g), within a 6-month period following the date of installation of the equipment, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of Need authorization. A party acquiring functionally related equipment or items, including those items and expenses listed in 111-2-2-.10(3)(d) within a 6-month period, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of need authorization;

(j) All simultaneously acquired and associated diagnostic and therapeutic equipment regardless of modality shall be aggregated. See the definition of "associated with and simultaneously developed or proposed." If additional diagnostic and therapeutic equipment is to be acquired, the party must submit price quotations for each piece of simultaneously acquired diagnostic and therapeutic equipment;

(k) A letter of non-reviewability for the acquisition of diagnostic or therapeutic equipment shall be valid only for the defined equipment, physical location, cost, and entity or person named in the request as the acquirer and operator of equipment and only to the pertinent facts that were disclosed in the request, except that cost may exceed the amount approved by the Department as long as the actual final expenditures do not exceed the equipment threshold. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of non-reviewability change in any way, the letter is no longer valid;

(l) Upon completion of the acquisition of the equipment, the party requesting a LNR shall submit a final statement of the total costs of the equipment, including separate line item valuation sheets with the same detail and documentation as required in subsections 111-2-2-.10(3)(d) through (h) above. In addition, if the if the equipment and associated activities are not completed within 180 days of the issuance of the LNR, the party requesting a LNR shall submit an interim statement within two weeks of the end of that 180 day period and within two weeks of the end of each succeeding 90 day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the expenses incurred to date, and any good faith estimates of the percentage of completion and the amount of costs expected to be incurred to complete. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a

LNR. Failure to comply with the provisions of this subsection may result in the rescission of the LNR issued.

(4) **Reserved.**

(5) **Administrative Remedies for Adverse Determinations.** When the Department makes a determination or decision or declines to issue a letter of non-reviewability pursuant to Sections 111-2-2-.10(1) through (4) of this rule or any other determination or decision over which the Health Planning Review Board lacks subject matter jurisdiction, the person who requests and receives the determination or decision may appeal to the Commissioner or his designee for an administrative hearing pursuant to the Administrative Procedures Act if such person is aggrieved by the Department's determination or decision. Such request for a hearing must be made in writing and must be received by the Department within 30 days of the date of the Department's determination or decision. If such written request is not received by the Department within 30 days, the Department's determination or decision shall become final upon the 31st day.

(6) **Persons Challenging Determinations and Letters of Non-Reviewability.** Interested persons may challenge a request for a letter of determination or letter or non-reviewability, as applicable, either during the Department's consideration of the request or within 30 days of the Department's issuance of the determination or letter of non-reviewability, as applicable. Challenges must be in writing and mailed to the Division of Health Planning at 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303. Upon receipt of a timely challenge, the following procedures will be in effect:

(a) The Department will forward the written challenge to the requestor or holder, as applicable, of the letter of determination or letter of non-reviewability. The requestor or holder, as applicable, shall have 10 business days to respond to the Challenge, unless such time is extended in the Department's sole discretion for good cause.

(b) Upon receipt of the requestor's or holder's response, the Department will forward the response to the challenger. If the challenger wishes to respond, the challenger shall have 10 business days to respond to the requestor's or holder's response, unless such time is extended in the Department's sole discretion for good cause.

(c) Should the challenger respond to the requestor's or holder's response, the Department will forward the challenger's response to the requestor or holder, as applicable. The requestor or holder shall have 10 business days to make a final response to the challenge.

(d) Upon receipt of the final response from the requestor or holder, the Department shall make a determination as to the merits of the challenge.

(e) Challenges shall be submitted pursuant to and in compliance with 111-2-2-.06(5). Challenges shall also include one signed original of the written vendor lobbyist certification required by 111-1-2-.03(2).

(f) This rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need. Furthermore, this challenge process shall

not be construed as a proceeding meeting the definition of “contested case” under the Georgia Administrative Procedure Act.

(g) If a determination or letter of non-reviewability is revoked or cancelled by the Department pursuant to these challenge provisions, the requestor or holder shall have appeal rights pursuant to 111-2-2-.10(5).

111-2-2-.11 Service-Specific Review Considerations Generally.

(1) The Department has adopted the following service-specific requirements and review considerations:

(a) Acute Care and Acute Care-Related Rules:

1. Short-Stay General Hospital Services, 111-2-2-.20;

2. Adult Cardiac Catheterization Services, 111-2-2-.21;

3. Open Heart Surgical Services, 111-2-2-.22;

4. Pediatric Cardiac Catheterization and Open Heart Services, 111-2-2-.23;

5. Perinatal Services, 111-2-2-.24;

6. Freestanding Birthing Center Services, 111-2-2-.25; and

7. Psychiatric and Substance Abuse Inpatient Services, 111-2-2-.26;

(b) Long-Term Care Rules:

1. Skilled Nursing and Intermediate Care Facility Services, 111-2-2-.30;

2. Personal Care Home Services, 111-2-2-.31;

3. Home Health Services, 111-2-2-.32;

4. Continuing Care Retirement Communities ("CCRC"), 111-2-2-.33;

5. Traumatic Brain Injury Services, 111-2-2-.34; and

6. Comprehensive Inpatient Physical Rehabilitation Services, 111-2-2-.35;

(c) Special and Other Health Services:

1. Ambulatory Surgical Services, 111-2-2-.40;

2. Positron Emission Tomography, 111-2-2-.41; and

3. Radiation Therapy Services, 111-2-2-.42.

(2) The review considerations and standards that are promulgated in service-specific rules are considerations and standards that apply to specific services in addition to the general considerations in 111-2-2-.09. Any conflict between the meaning or application of a service-specific requirement and the general considerations shall be interpreted in favor of

the service-specific consideration, unless a general consideration specifically indicates that it supercedes any and all service-specific considerations.

(3) The meaning of words as they are defined in a particular service-specific rule only applies to that service-specific rule, unless a specific citation is made to another service-specific rule.

(4) Numerical Need Calculations.

(a) The numerical need calculations, which shall apply to an application for a clinical health service for which service-specific rules exist, shall be the calculated need in effect on the date the application is deemed complete for review less any subsequently approved units and services during the review period. This provision does not apply to batching reviews as the need applicable to batching decisions is the need stated in the batching notice.

(b) In the instance of joined projects where one project is reviewed as an exception based on utilization and the other is reviewed as need-based, the approval of the utilization exception shall not preclude an approval based on a numerical need projection should, prior to the approval of any of the joined projects, the numerical need projection indicates a need for the clinical health service.

(c) Approved projects that affect service-specific numerical need calculations shall be added to the Department's service-specific inventories and the numerical need projections shall be adjusted as of the approved date of the project.

(d) Approved projects that are reversed through administrative and/or judicial appeal final resolution shall be subtracted from the Department's service-specific inventories and the numerical need projections shall be adjusted as of the date of such final resolution.

(5) As provided in this rule, unless an applicable service-specific rule specifically requires review for a replacement facility or service under the applicable service-specific considerations, the Department shall review an application for a replacement health care facility or service at an alternate location from the defined location solely under the general considerations of 111-2-2-.09 if the following conditions are met:

(a) the health care facility or service has received prior CON review and approval or has been grandfathered;

(b) if a facility or service currently requires review under a service-specific rule, the prior CON review and approval included review under a service-specific need calculation or exception thereto;

(c) the alternate location of the replacement facility is not more than 3 miles from the defined location of the CON-approved facility or service;

(d) the alternate location of the replacement facility is within the same county as the CON-approved facility or service; and

(e) the replacement does not otherwise qualify as an expanded service under a service-specific rule.

(6) Service-specific component plans provide general background on specific considerations that were undertaken in developing service-specific rules. The service-specific rules shall supercede component plan.

(7) If any provision of these service-specific rules, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the particular service-specific rule in question or of the service-specific rules in general which can be given effect without the invalid provision or application, and to this end the provisions of these service-specific rules are severable.

RULES
OF
DEPARTMENT OF COMMUNITY HEALTH
DIVISION OF HEALTH PLANNING

CHAPTER 272-2
CERTIFICATE OF NEED

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272-2-.07 Exclusions.

(1) Repealed.

(2) Repealed.

(3) Repealed.

(4) Repealed.

(5) When the Department receives a request for a Letter of Nonreviewability (LNR) for the establishment of a physician-owned, single specialty, office-based ambulatory surgery facility, pursuant to O.C.G.A § 31-6-2(14)(G)(iii), the party requesting such a letter must comply with the following:

(a) Identify the name and address of the proposed ambulatory surgery facility, including the principal business address of the sole physician or group practice that will own the facility.

(b) Identify the individual private physician, or all owners (e.g., stockholders, partners, members) of the single group practice of private physicians who are also of the same single specialty, that will own, operate, and utilize the proposed facility. All members of the single group practice must be of the same specified surgical specialty. Physicians who perform procedures within the ambulatory surgery facility must own at least eighty-five (85) per cent of the group practice and the surgery center. The Department will issue a LNR, if all other criteria are met, to a single group practice which utilizes the services of employee physicians of the same specialty in the

surgery center if these employee physicians are not a member or employee of any other medical practice. All employee physicians must be identified, and an affirmative statement with regard to their practice affiliation must be included. The Department will allow no more than fifteen (15) per cent non-physician ownership in the physician (s) practice requesting a LNR, and/or the surgery center. Evidence of non-physician ownership, including the percentage of such ownership, must be provided with the LNR request.

(c) All physicians must be licensed to practice in the state of Georgia, and must submit a copy of such license; should any physician members of a single group practice perform procedures in the ambulatory surgery facility created by the issuance of a LNR lose their license to practice medicine in Georgia, the LNR shall be revoked, unless within sixty (60) days of such physician losing their license, the group practice submits new evidence documenting that the physician ownership of the facility by the group practice does not include the physician who lost their license.

(d) Submit evidence of the sole physician professional corporation or the entity comprising the single group practice of private physicians, to include authorizing and governing documents such as articles of incorporation, by-laws, operating agreements, partnership agreements, etc. Submit a sworn affidavit, signed by the owners, which lists all owners of the sole or group practice and the proposed surgery facility.

(e) The physician(s) must show evidence of ownership by warranty deed or lease of the space housing the ambulatory surgery facility including the clinical office space.

(f) Provide a detailed description of the proximity of the physician's or the group practice's clinical offices to the ambulatory surgery facility. The Department will only grant a LNR to those proposed ambulatory surgical facilities, which are deemed to be in reasonable proximity to the clinical offices of the sole physician or single group practice that will own the proposed facility. Reasonable proximity will be determined on a case-by-case basis. Examples of reasonable proximity include those ambulatory surgical facilities on the same floor and physically attached to the clinical offices; surgical suites on a different floor of the same building as the clinical offices with one public entrance to the proposed facility.

(g) State the number of operating rooms in the proposed ambulatory surgery facility.

(h) State the total square footage in the proposed ambulatory surgery facility. This total includes the square footage associated with all operating suites, reception and waiting areas, business offices, pre and post-operation areas, all building common areas including a pro rata share of the common areas of buildings utilized by multiple tenants, which are new and/or renovated and involve expenditures to be incurred in the development, construction and establishment of the proposed surgery facility.

(i) List costs attributable to new construction or renovation of the total area comprising the ambulatory surgery facility. Documentation of the total cost of constructing, developing, and establishing the proposed ambulatory surgical facility, and the costs of all items associated with or simultaneously developed with the project, including, but not limited to, fixed equipment not included in the construction contract, moveable

equipment, architectural and engineering fees, legal and administrative fees, interim financing (interest during construction), and underwriting costs. The documentation of construction and renovation costs must be in the form of a letter from a licensed Georgia architect verifying the estimated construction costs of the proposed ambulatory surgery facility. With regard to the construction of a new building (or a new wing including space devoted to services other than the surgery center) to house an ambulatory surgery facility, a pro-rata portion of the building shell costs, including all building common areas, must be allocated to the costs of the proposed ambulatory surgery facility. Other costs to be included are:

1. The cost of new space (even if the space will be leased) based on the construction cost of the new space. Appropriate documentation from an architect licensed in Georgia must be submitted. A copy of all leases must be submitted;
2. The cost of all equipment (medical and non-medical) purchased for the ambulatory surgery facility.
3. The present value of any equipment to be leased for the surgery facility.
4. The Department must have a line item breakdown of all amounts attributable to new construction, renovation, furnishings, leases, and items of equipment in accordance with the provisions outlined above, including new expenditures for furnishings for non-patient care areas such as waiting areas, reception areas, and business offices.

The Department will require a sworn affidavit that no party associated with the practice or physicians requesting a LNR, by virtue of ownership or employment, has incurred any expenditure for equipment or employment, has incurred any expenditure for equipment of any kind to be utilized in the surgery center that has been subsequently donated to the practice for use in the surgery center and the cost of that equipment, whether purchased or leased, was not included in the dollar threshold applicable to the surgery center.

(j) A schematic floor plan must be provided to the Department. This documentation must be clear and readable. The floor plan must clearly show all areas of the proposed ambulatory surgery facility.

(k) Pursuant to O.C.G.A. § 31-6-2(14), list the cost of all other items, regardless whether they are independently subject to Certificate of Need review, that are associated and to be simultaneously developed with the proposed ambulatory surgery facility, except for the expenditure or commitment of funds to develop studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites.

(l) The Department will not issue a LNR to any sole physician or single specialty group practice of physicians proposing to bill a professional fee through a larger multi-specialty group practice in which the single specialty group practice requesting the LNR remains a part of. For purposes of these rules, this provision does not preclude the issuance of a LNR to a physician(s), which utilizes a larger group practice for the sole purpose of billing services under the provider number of the sole physician or single group practice.

(m) The Department will not issue a LNR to any physician(s) who is a member of more than one single group practice, pursuant to O.C.G.A. § 43-1B-3(5) of the Georgia Patient Self-Referral Law.

(n) The Department will not issue a LNR to any group practice of physicians if any members of that group practice are also members of a multi-specialty clinical practice. For purposes of these rules a multi-specialty clinical group practice does not mean any volume purchasing association or managed care network whose function is managed care contracting in which the physician or group practice participates.

(o) The Department will not issue a LNR to any party proposing to share operating rooms or common space in a proposed ambulatory surgical facility between more than one group practice of the same specialty or between more than one surgical group practice of different specialties, or between more than one sole physician of the same or different specialties who are not members of the same medical practice.

(p) Provide a sworn affidavit, signed by the physician(s) owners, that the party requesting a LNR will not incur any additional capital expenditures involving new construction or renovation of physical space or the addition or replacement of equipment within three years after the issuance of the LNR, which, when coupled with prior expenditures, would exceed the threshold amount applicable to the statutory exemption for this type of facility unless it first secures a Certificate of Need. A party holding a LNR issued by the Department may request, in writing, a waiver from this provision for expenditures for equipment involving newly recognized and innovative medical technologies (FDA approved) present in the marketplace. Any such expenditure will be applied to the original threshold amount unless the written consent of the Department is obtained prior to the expenditure.

(q) Upon completion of construction of the ambulatory surgery facility, the party requesting a LNR shall submit a final statement of the total costs of the facility, including a separate line item completed project cost sheet with the same detail and documentation as required in subsection (J) above. In addition, if the proposed ambulatory surgery facility is not completed within 180 days of the issuance of a LNR, the party requesting a LNR shall submit an interim statement within two weeks of the end of that 180 day period and within two weeks of the end of each succeeding 90 day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the cost of the facility incurred to date, and any good faith estimates of the percentage of completion of the facility and the amount of costs expected to be incurred to complete the facility. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a LNR and from the general contractor. Failure to comply with the provisions of this subsection may result in the rescission of the LNR issued.

(r) The LNR is not transferable to a purchaser of the sole physician or single group practice, which originally received a LNR. This provision is not intended to limit the transferability of a sole physician practice or a group practice, but is intended to put the new physician owners on noticed that they must request a new LNR as new owners of that practice. Such a new request will be evaluated based on the LNR

criteria applicable at the time of the new request, and the acquisition costs of the practice will not be a part of the applicable capital expenditure threshold.